

Environmental Protection Agency



Office of Pesticide Programs

eDossier Builder User Guide

Version 2.1

December 18, 2013

Prepared by:



*Ace Info Solutions, Inc.
11490 Commerce Park Drive, Suite 340
Reston, Virginia 20191*

Table of Contents

1	INTRODUCTION.....	1
1.1	SYSTEM OVERVIEW	1
1.2	PURPOSE	1
1.3	SCOPE	1
2	INSTALLATION.....	2
2.1	PREREQUISITES	2
2.2	ADOBE AIR	2
2.3	EDOSSIER BUILDER.....	5
2.3.1	<i>Install</i>	5
2.3.2	<i>Uninstall</i>	7
3	OPEN EDOSSIER BUILDER & USING THE TOOLBAR.....	10
3.1	OPEN EDOSSIER BUILDER	10
4	CREATE, EDIT, & DELETE COMPANY PROFILE	11
4.1	CREATE A COMPANY PROFILE	11
4.2	EDIT A COMPANY PROFILE	13
4.3	DELETE A COMPANY PROFILE.....	14
5	CREATE, EDIT, AND DELETE A NON-EDSP PACKAGE	16
5.1	CREATE A NON-EDSP PACKAGE	16
5.2	CONTINUE A SAVED NON-EDSP PACKAGE	22
5.3	ADD/EDIT PACKAGE METADATA.....	24
5.4	ADD/EDIT PACKAGE LEVEL DOCUMENTS.....	27
5.5	OPEN PACKAGE LEVEL DOCUMENTS	30
5.6	DELETE A PACKAGE.....	31
6	ADD, EDIT, & DELETE NON-EDSP APPLICATION METADATA & DOCUMENTS	33
6.1	PROVIDE AN APPLICATION TITLE.....	33
6.2	ADD/EDIT APPLICATION METADATA.....	35
6.3	ADD/EDIT APPLICATION LEVEL DOCUMENTS.....	38
6.4	OPEN APPLICATION LEVEL DOCUMENTS	44
6.5	ADD AN APPLICATION	45
6.6	DELETE AN APPLICATION	51
7	VALIDATE & FINALIZE A NON-EDSP PACKAGE.....	53
8	CREATE, EDIT, AND DELETE AN EDSP PACKAGE.....	55
8.1	CREATE AN EDSP PACKAGE.....	55
8.2	CONTINUE A SAVED EDSP PACKAGE	61
8.3	ADD/EDIT PACKAGE METADATA.....	64
8.4	ADD/EDIT PACKAGE LEVEL DOCUMENTS.....	67
8.5	OPEN PACKAGE LEVEL DOCUMENTS	73
9	VALIDATE & FINALIZE AN EDSP PACKAGE	75
10	TOOLBAR	77
10.1	HOME.....	77
10.2	ABOUT	78
11	SYSTEM HELP	79
12	CONFIGURATION.....	82

12.1 PACKAGE STORAGE LOCATION 82

12.2 APPLICATION FONT SIZE 85

 12.2.1 Permanent 85

 12.2.2 Current Session 86

13 EXIT..... 87

APPENDIX A: NON-EDSP DATA FIELDS 88

APPENDIX B: DATA FIELDS FOR EDSP PACKAGES 95

1 Introduction

1.1 System Overview

The eDossier Builder system, developed by the Environmental Protection Agency (EPA) Office of Pesticide Programs (OPP), allows registrants to create packages for electronic submission in a user-friendly manner and presents packages to EPA systems in a specified format. Specifically, eDossier Builder allows registrants to create the following packages:

Registration Packages:

- New Product Registrations
- Experimental Use Permits
- Tolerance Petitions
- Distributor Products
- *Inert Ingredient Requests
- *Pre-Applications
- *FFS Waiver Requests

** Regulatory type packages that are not supported by the current electronic submission system.*

EDSP Packages:

- Individual order responses
- Consortia response for multiple orders

The package created consists of all documents and metadata that is required by EPA to properly process the package. Once all documents and metadata are provided, they are packaged together and stored in a single zip file for delivery to EPA.

1.2 Purpose

The purpose of this document is to provide instructions on how to use the eDossier Builder application. More precisely, the document provides instructions for installing the application, configuring the application, providing company profile information, creating a package, and completing other miscellaneous functions (e.g., viewing version information, viewing help, etc.).

1.3 Scope

The scope of this document is limited to the eDossier Builder application. All other applications are outside the scope of this document.

The document was developed using eDossier Builder v1.0 and will be updated as needed.

2 Installation

2.1 Prerequisites

The prerequisites for installing eDossier Builder include the following:

- Internet Explorer version 6.0, 7.0, or higher/Mozilla Firefox version 6.0 or higher/Chrome Browser version 15.0.874.106 m or higher (Required for installing Adobe Air according to the installation instructions provided in section 2.2)
- Adobe AIR version 3.0 or higher (Installation instructions provided below in section 2.2). Note: Adobe AIR might have its own systems requirements, which are out of scope of this document.

2.2 Adobe AIR

1. Open **Internet Explorer** and go to <http://get.adobe.com/air/>
2. The *Adobe Air Download* web page appears. Select the **Download now** button.

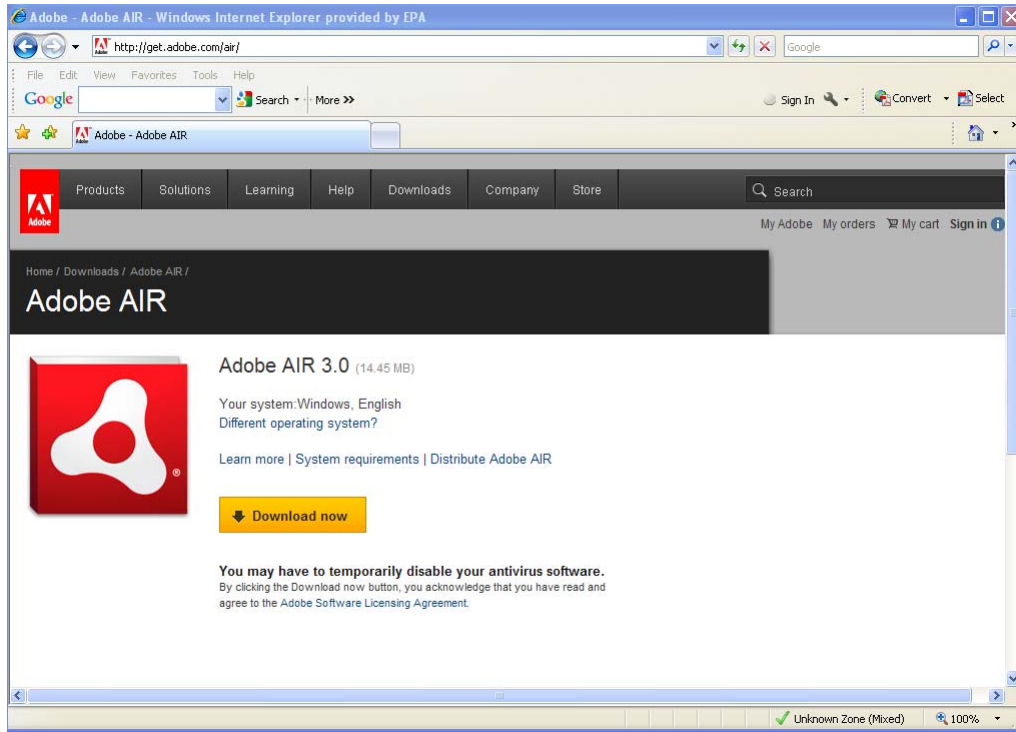


Figure 2-1: Adobe AIR Download

3. The *File Download – Security Warning* window appears. Select the **Run** button.

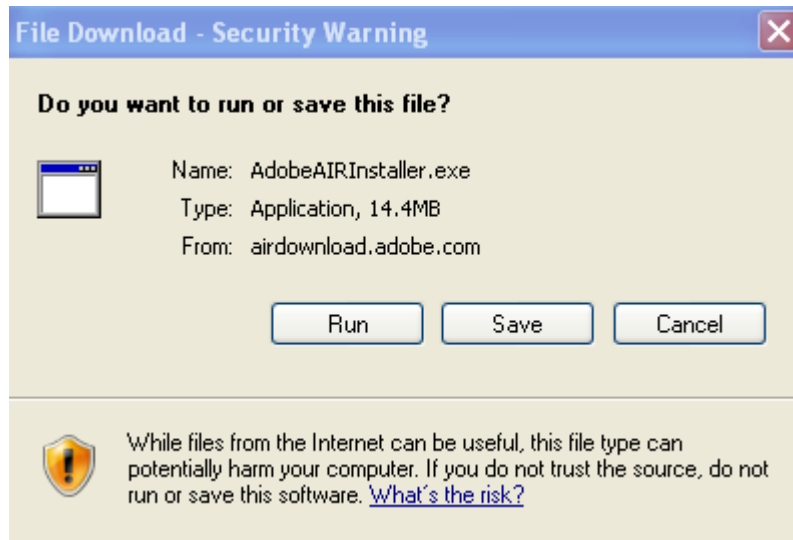


Figure 2-2: File Download – Security Warning

4. The *Internet Explorer – Security Warning* window appears. Select the **Run** button.

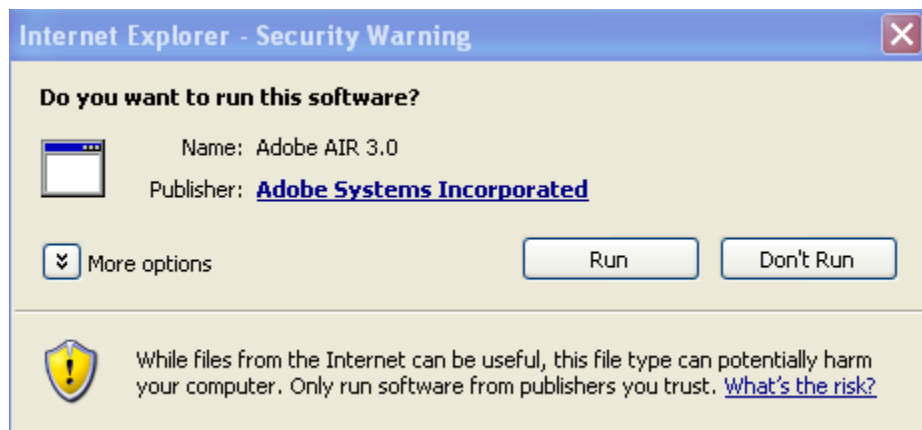


Figure 2-3: Internet Explorer – Security Warning

5. The *Adobe AIR Setup* window appears. Select the **I Agree** button.

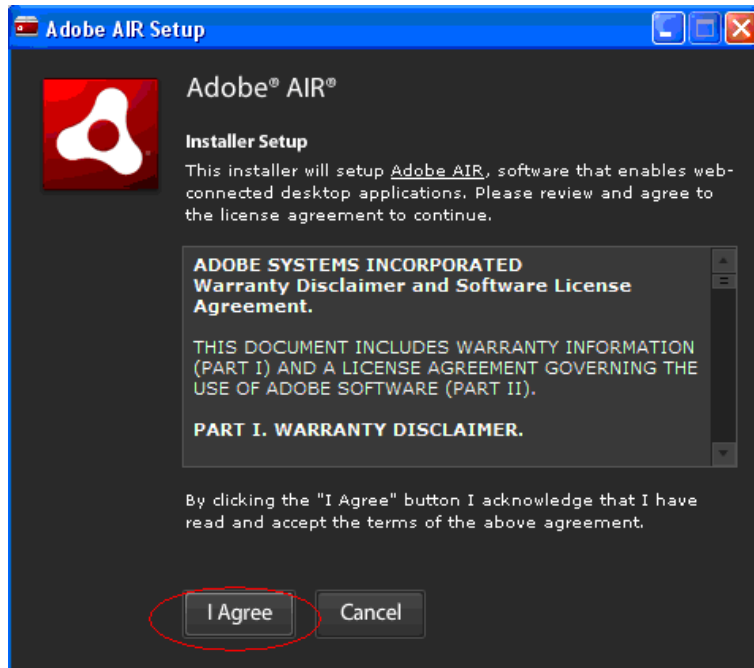


Figure 2-4: Adobe AIR – Installer Setup

While Adobe AIR is being installed, the *Adobe AIR Setup – Installation Status* window appears.

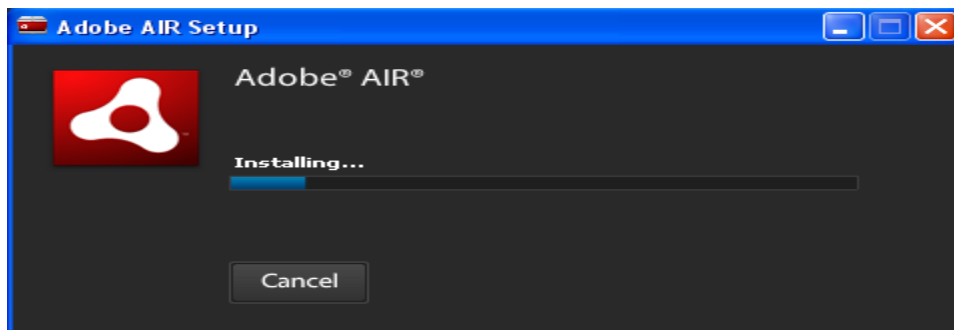


Figure 2-5: Adobe AIR – Installation Status

6. Once the installation has been completed, the *Adobe AIR Setup – Installation Completed* window appears. Select the **Finish** button.

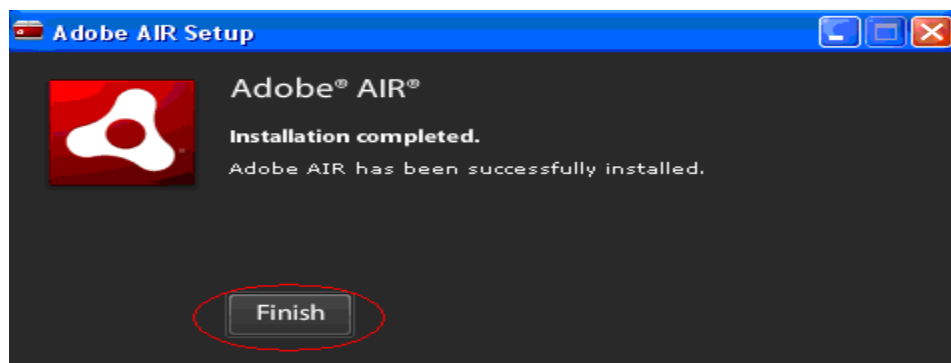


Figure 2-6: Adobe AIR – Installation Completed

2.3 eDossier Builder

Note: Uninstall any previous versions of eDossier Builder before installing version 1.0. Instructions for uninstalling the previous build are in section 2.3.2 (Uninstall) of this document.

2.3.1 Install

Note: Prior to installing, Adobe AIR must be installed on your computer. If not installed, follow the instructions provided in section 2.2 (Adobe AIR).

1. Open the eDossier Builder “exe” file.

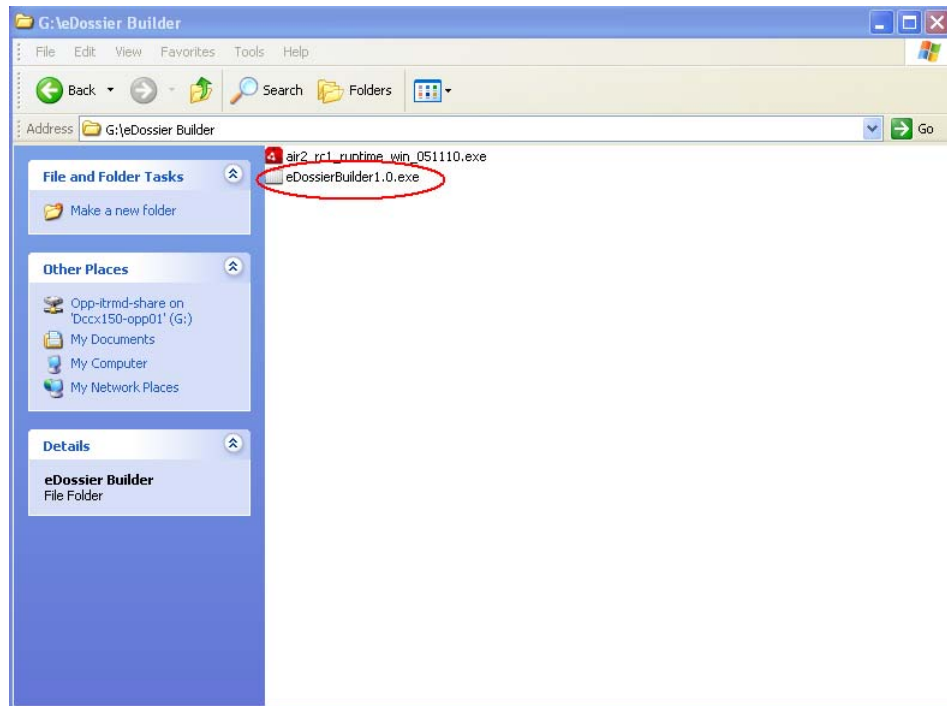


Figure 2-7: eDossier Builder exe File

2. The *Application Install* screen appears.

Note: By default, both *Installation Preference* boxes are selected, and the *Installation Location* is set to **C:\Program Files**. Deselect any of the *Installation Preferences* you would like disabled. If you would like to change the location of the application, select the **folder icon** and select another location.

Select the **Continue** button.

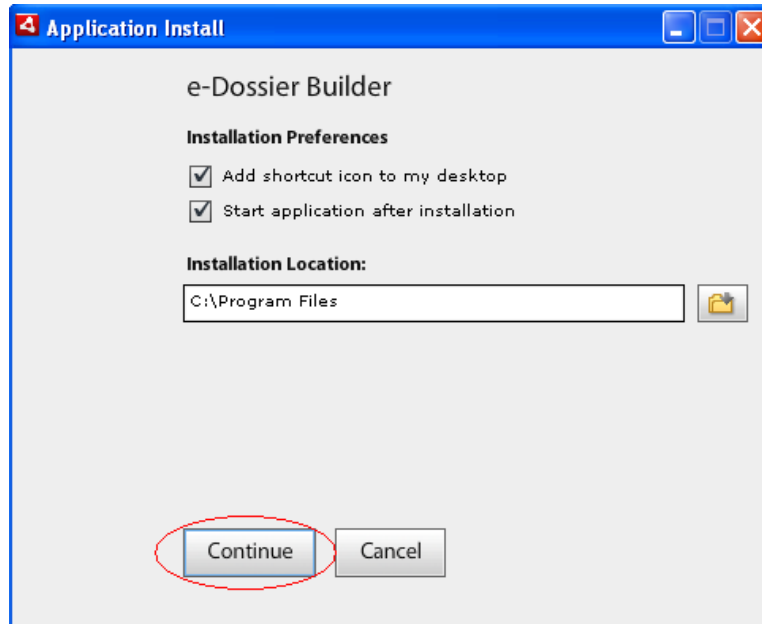


Figure 2-8: Application Install

The *Application Install Progress* screen appears briefly while the application is being installed.

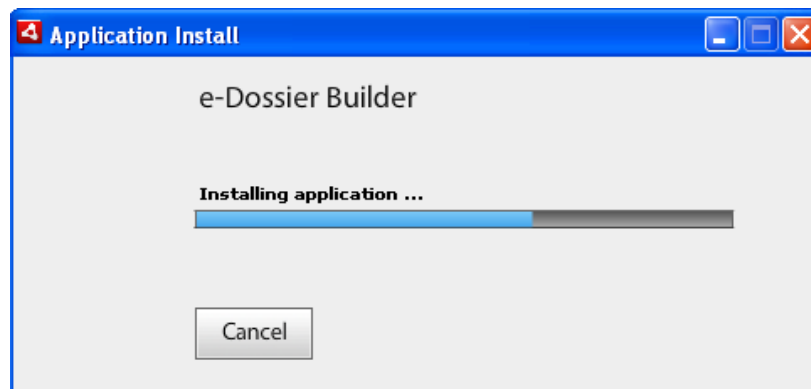


Figure 2-9: Application Install Progress

3. Once the application has finished installing, the *Application Install* screen will automatically close and the eDossier Builder *Home* screen appears. The application will not open if you chose for the application to not open at the completion of installation during step 2.

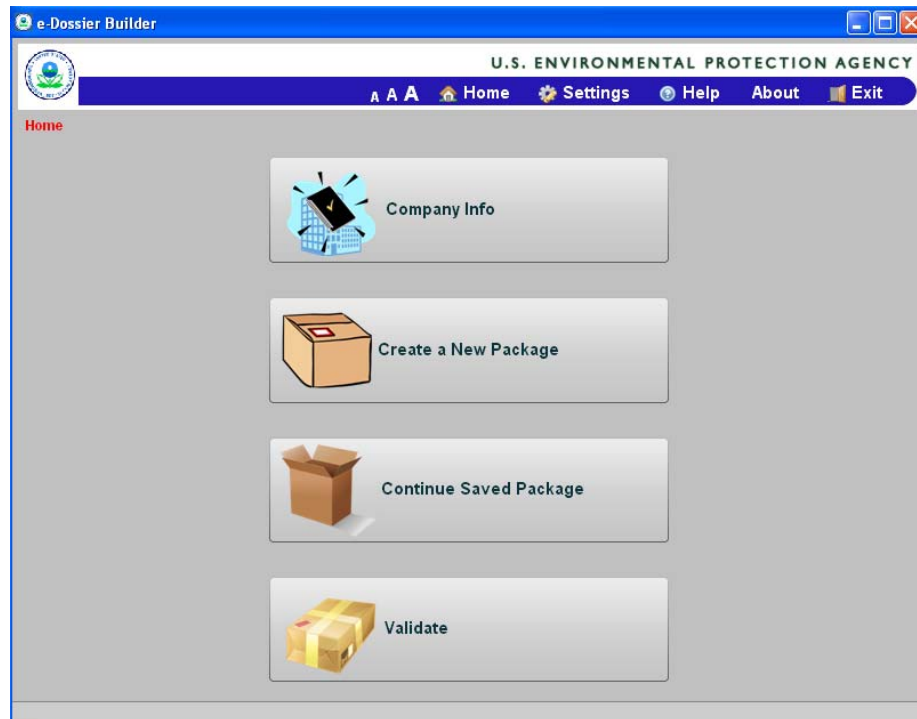


Figure 2-10: eDossier Builder Home Screen

2.3.2 Uninstall

If you would like to uninstall the application, follow the steps listed below.

1. From your computer, select **Start > Control Panel**.

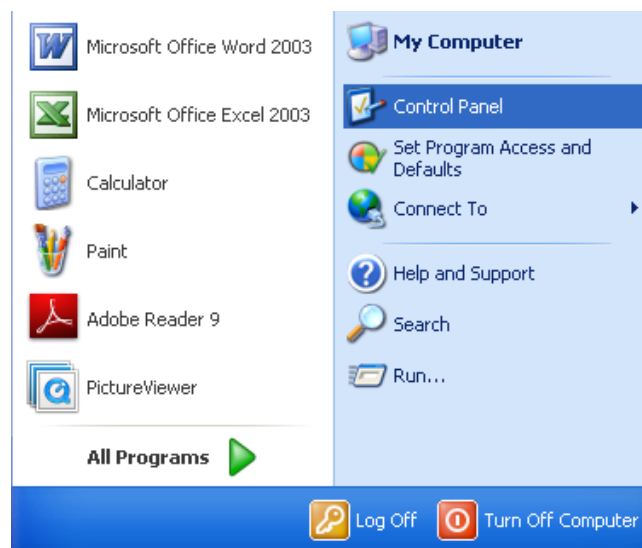


Figure 2-11: Open Control Panel

- The *Control Panel* window appears. Select the **Add or Remove Programs** icon.

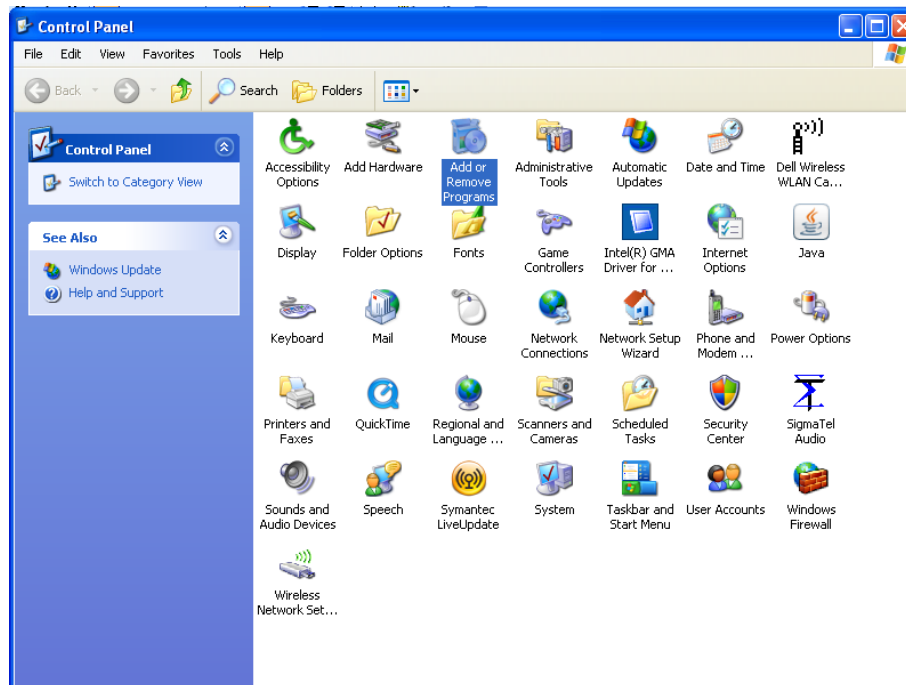


Figure 2-12: Control Panel

- The *Add or Remove Programs* window appears. Select **eDossier Builder**, and then click the **Remove** button.

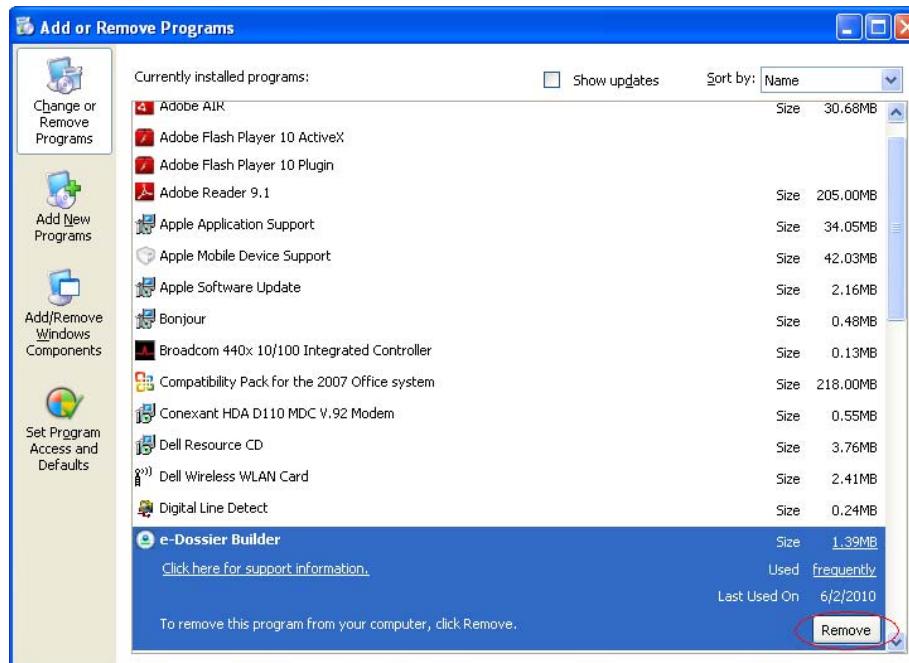


Figure 2-13: Add or Remove Programs

4. The *eDossier Builder Uninstall Progress* window appears as the application is being removed from your computer. Once complete, the window will close and eDossier Builder will no longer be listed in the *Add or Remove Programs* window.

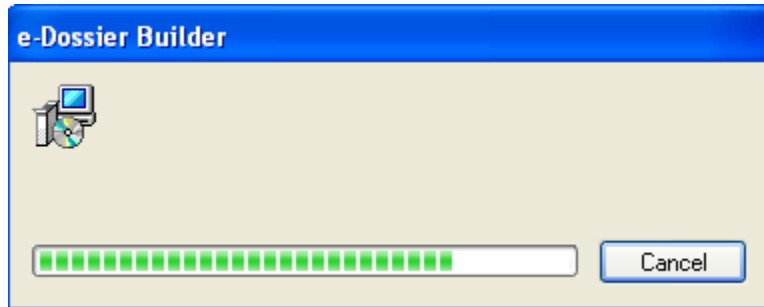


Figure 2-14: eDossier Builder Uninstall Progress

3 Open eDossier Builder & Using the Toolbar

3.1 Open eDossier Builder

1. Go to the location where eDossier Builder was placed during installation. By default, and if not changed during installation, an icon is provided on the computer desktop.
2. Click on the **eDossier Builder icon** to open the application.

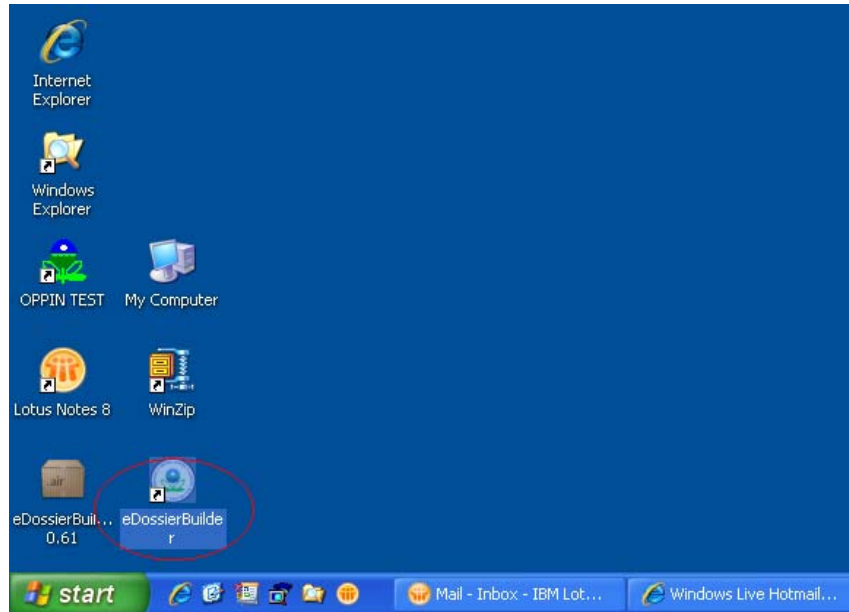


Figure 3-1: eDossier Builder Icon

3. The *Home* screen appears.

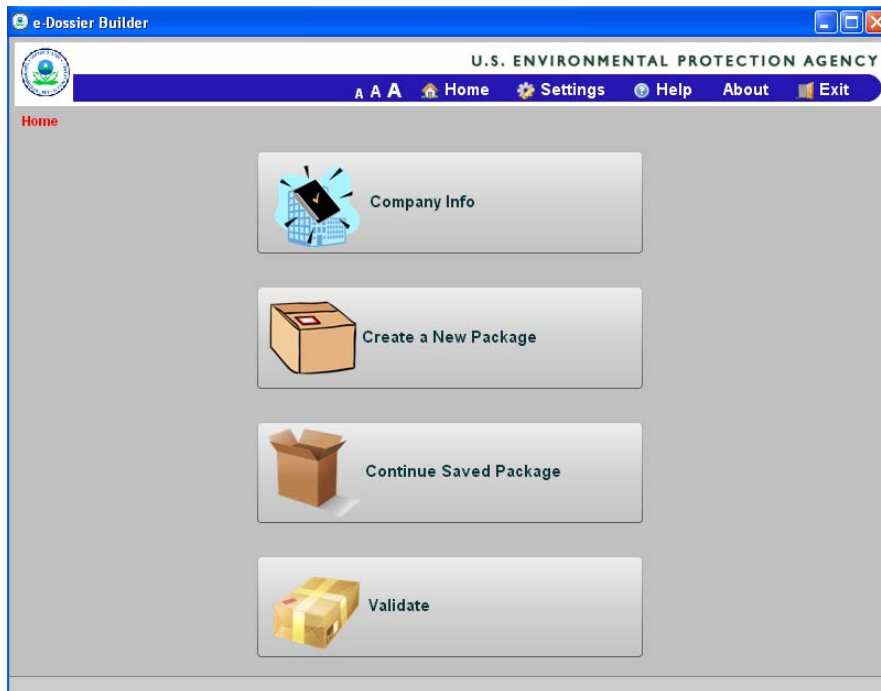


Figure 3-2: Home Screen

4 Create, Edit, & Delete Company Profile

4.1 Create a Company Profile

Company Profile is the name given to the profile created in the 'Company Info' screen. This field can have numeric or string values, or any combination (e.g., alpha01). A minimum one Company profile is mandatory for creating an electronic package.

1. From the *Home* screen, select the **Company Info** button.

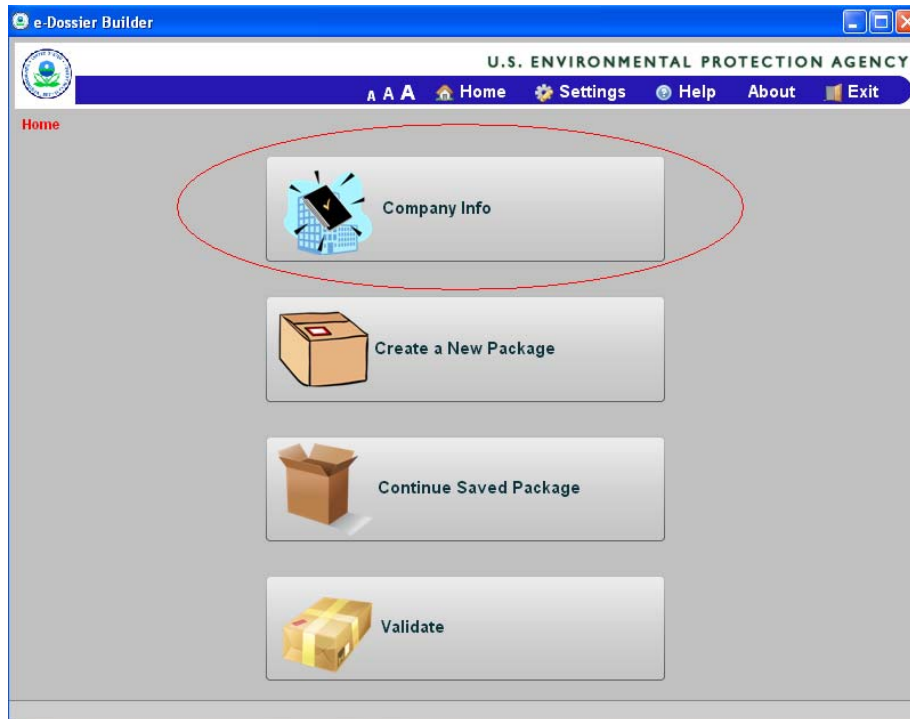


Figure 4-1: Company Info Selection

- The *Company Profile* screen appears. Complete all **required fields** (*) and any of the other fields as necessary, and then select the **Add Profile** button.

Note: The Company and Contact Details are not meant to be the official company contact information.

The screenshot shows the 'e-Dossier V1.05' application window. The title bar includes the EPA logo and the text 'U.S. ENVIRONMENTAL PROTECTION AGENCY'. The menu bar contains 'Home', 'Settings', 'Help', 'About', and 'Exit'. The main content area is titled 'Company Profile' and contains a table with the following data:

Profile Name	Company Name	Company Number	Contact Name
Clearwater	Clearwater Chemical	12345	
Clearwater1		123456	
Profile 1		12345	

Below the table are buttons for 'Edit Profile' and 'Delete Profile'. Further down are form fields for 'Profile Name *', 'Description', 'Company Name', 'Company Number *', 'Country' (set to 'UNITED STATES'), and 'Contact Details' (Name). A red note states: '(Company Description is Optional for internal use by company, not for public release)'. At the bottom right, the 'Add Profile' button is circled in red, next to a 'Cancel' button.

Figure 4-2: Company Info Screen

- The information entered is now provided in the *Company Information* table as shown below. Repeat step 2 if you would like to provide additional profiles. If no other company profiles are needed, select **Home** from the tool bar provided at the top of the screen.

The screenshot shows the 'e-Dossier Builder' application window. The title bar includes the EPA logo and the text 'U.S. ENVIRONMENTAL PROTECTION AGENCY'. The menu bar contains 'Home', 'Settings', 'Help', 'About', and 'Exit'. The main content area is titled 'Company Profile' and contains a table with the following data:

Profile Name	Company Name	Company Number	Contact Name	Title
Profile 1	Jon Doe's Chemical	12345	Jon Doe	Chemical Specialist
Profile 2	Jon Doe's Chemical	54321	Jon Doe	Chemical Specialist
Profile 3	Jon Doe's Chemical	010203	Jane Doe	Chemist

Below the table are buttons for 'Edit Profile' and 'Delete Profile'. In the menu bar, the 'Home' button is circled in red. At the bottom right, the 'Add Profile' button is circled in red.

Figure 4-3: Company Info Added

4.2 Edit a Company Profile

1. From the *Company Profile* screen, select a profile that is provided in the *Company Information* table, and then click the **Edit Profile** button.

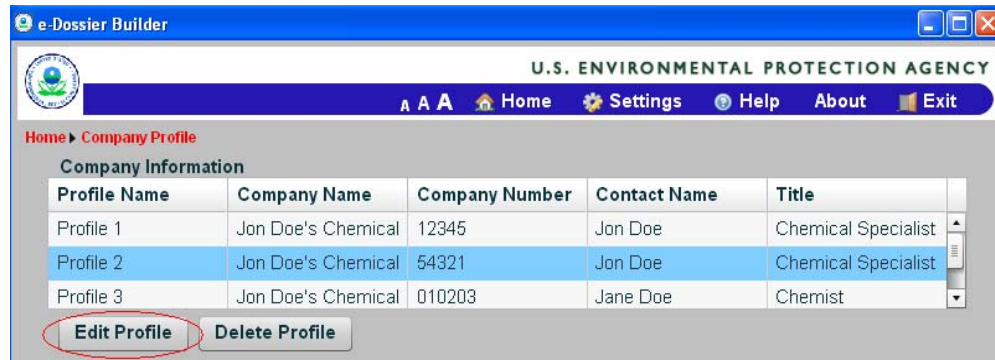


Figure 4-4: Edit Company Info

2. The previously entered profile name and company and contact details are provided in their associated fields located below the *Company Information* table. Make any **required changes**, and then select the **Save Profile** button.

The screenshot shows the 'e-Dossier Builder' application window. The title bar reads 'e-Dossier V1.05'. The menu bar includes 'Home', 'Settings', 'Help', 'About', and 'Exit'. The breadcrumb trail is 'Home > Company Profile'. Below this is the 'Company Information' section, which contains a table with the following data:

Profile Name	Company Name	Company Number	Contact Name
Clearwater	Clearwater Chemical	12345	
Clearwater1		123456	
Profile 1		12345	

Below the table are two buttons: 'Edit Profile' and 'Delete Profile'. Below these buttons are several form fields:

- Profile Name * Profile 1
- Description (Company Description is Optional, for internal use by company, not required)
- Company Details
- Company Name
- Company Number * 12345
- Country (UNITED STATES)
- Contact Details
- Name

At the bottom right, there are two buttons: 'Save Profile' (circled in red) and 'Cancel'.

Figure 4-5: Save Company Profile Changes

- The company profile changes are saved and the profile information is provided in the *Company Information* table.

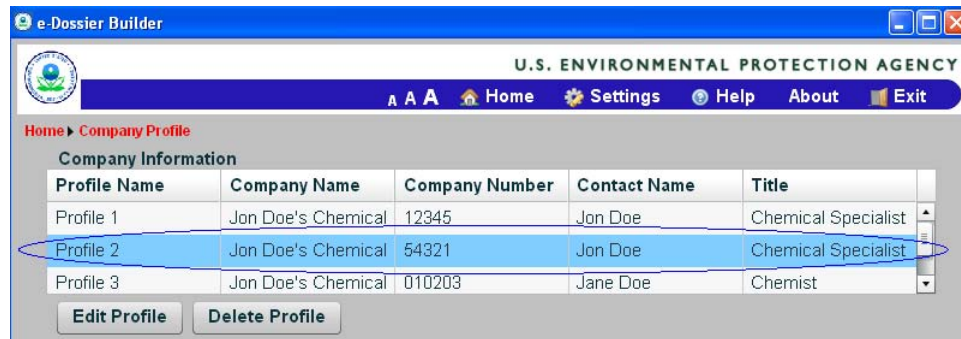


Figure 4-6: Updated Company Profile

4.3 Delete a Company Profile

- From the *Company Profile* screen, select a profile that is provided in the *Company Information* table, and then click the **Delete Profile** button.

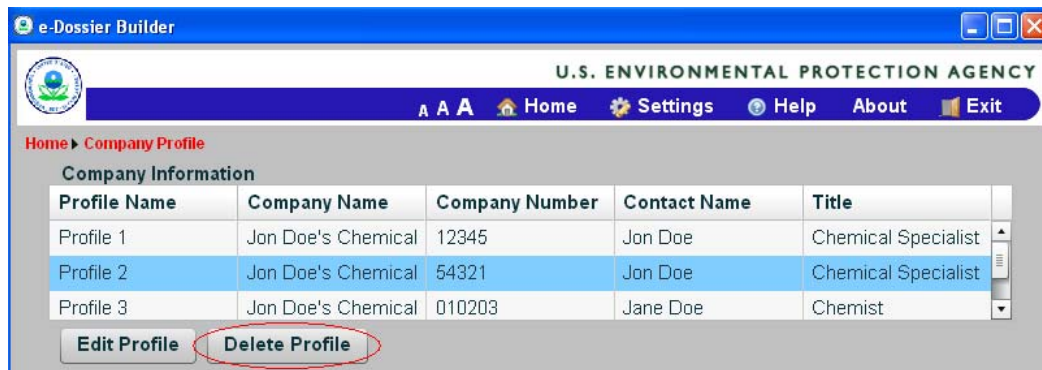


Figure 4-7: Company Profile Delete

- The *Delete* window appears asking if you want to delete the profile. Select the **Yes** button.

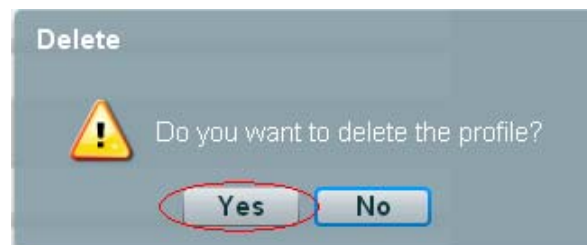


Figure 4-8: Delete Window

- The previously provided company profile is removed from the *Company Information* table as shown below.

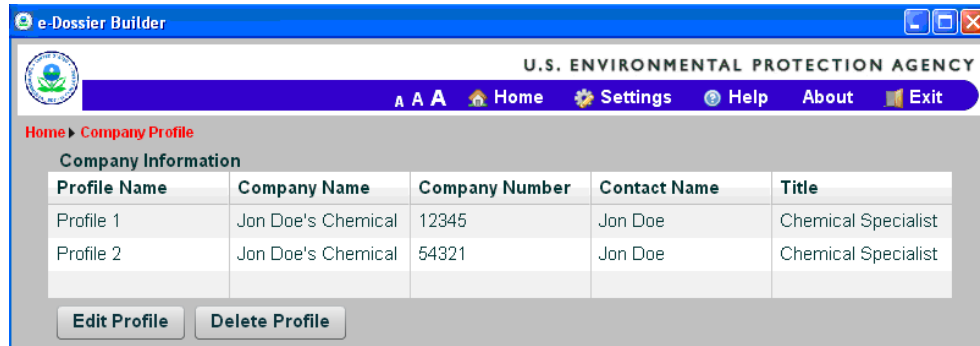


Figure 4-9: Company Profile Deleted

5 Create, Edit, and Delete a Non-EDSP Package

5.1 Create a Non-EDSP Package

1. From the *Home* screen, select the **Create a New Package** button.

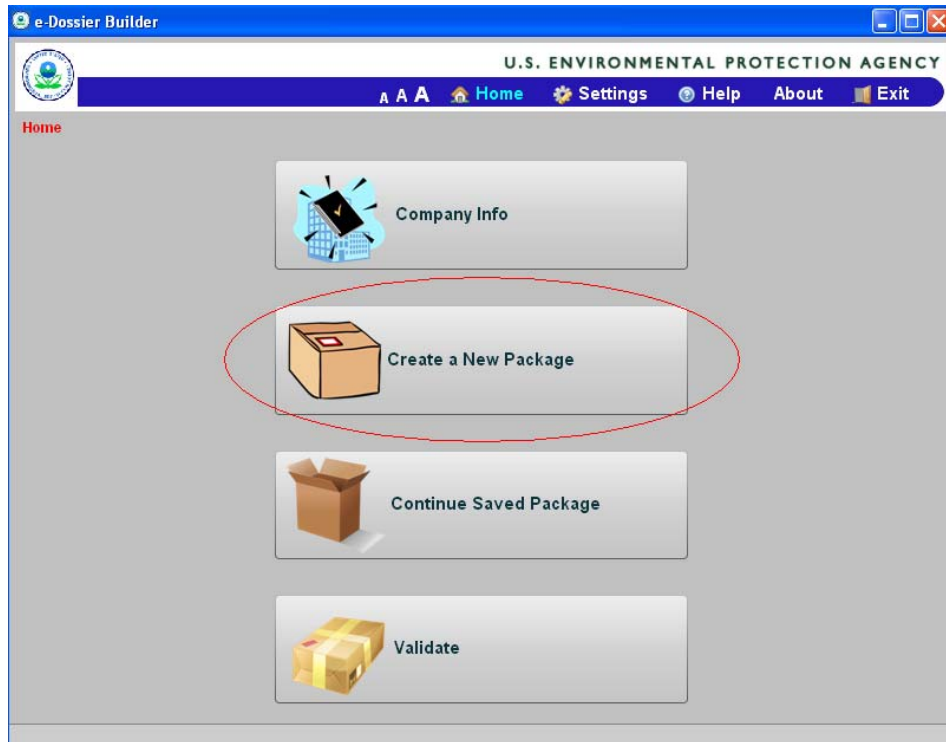


Figure 5-1: Create a New Package

2. The *Confirmation Page* appears. Click on the **No** button for creating a **Non-EDSP package**.

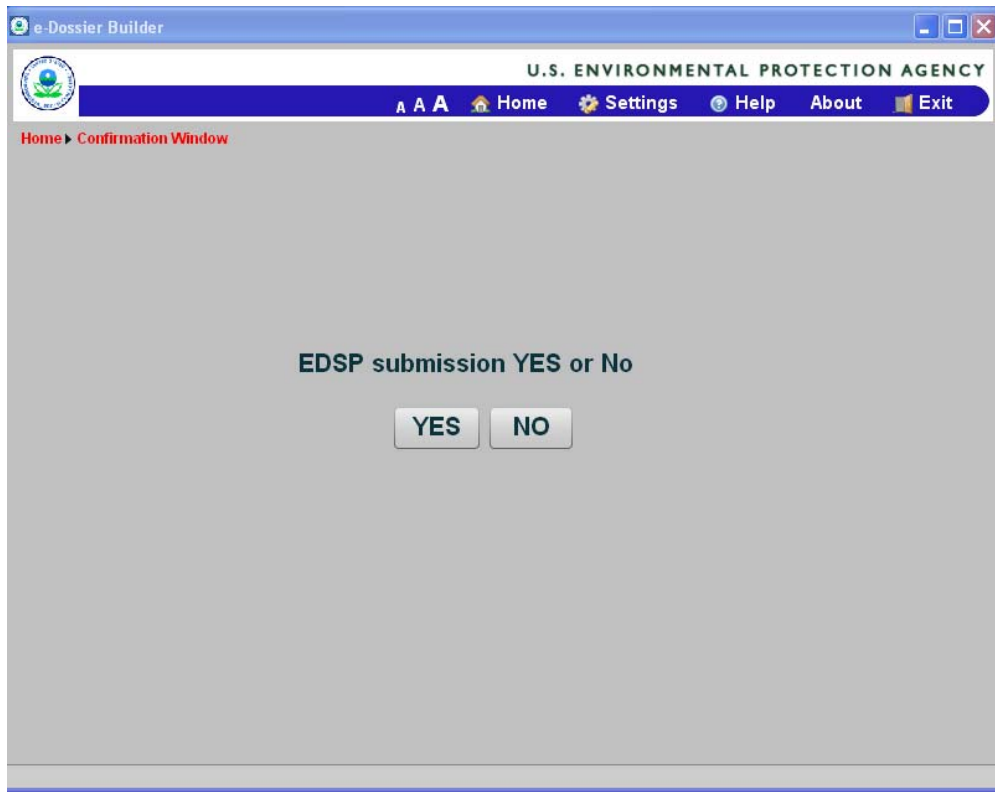


Figure 5-2: Create a EDSP Package Yes or No

- The *New Package for Non-EDSP Orders* screen appears. Complete all **required fields** (*) and any of the other fields as necessary, select the applicable **Regulatory Type** (i.e., Product Registration – Section 3) and **Application Type** (i.e., New Registration and the number of applications to be added under each type), and then select the **Next>** button.

e-Dossier V1.05

U.S. ENVIRONMENTAL PROTECTION AGENCY

Home Settings Help About Exit

Home > New Package

Package Info

Package Name * Chemical B Product Registration

Description * (Package Description is Optional for internal use by company, not Currently)

Email sample@company.com

Is this PRIA? ☒ (Check this if this submission is subject to PRIA Fees)

*PRIA is Optional Future Use, not Currently used by EPA

Company Profile * Profile 1

Which components are included?

☐ Distributor Product

☒ Experimental Use Permit - Section 5

☐ Amendment 1

☒ New Registration 1

☐ Inert Ingredient Request

Next >

Figure 5-3: Package Info

4. The *Document for the Package* screen appears. Complete all **required fields (*)** and any of the other fields as appropriate, and then select the **Add Document** button.

Note: A Package is the entire collection of documents/files being submitted at one time. A Package will include one or more applications each to fulfill a specific regulatory need (e.g., applications to register a section 3 product or EUP, application to amend section 3 registrations, or to submit a petition to establish tolerances).

Documents at the package level will apply to the entire set of one or more applications and typically include cover letters, fee payment receipts and OECD Dossier documents.

Documents at the application level will include the forms, labels, studies and other supporting documents/files specific to an individual application.

Figure 5-4: Add Package Document

5. The document information is provided in the *Documents* table as shown below.

Note: When adding multiple documents, the last document added will be placed at the bottom of the *Documents* table. Additionally, documents are not officially attached until the package is finalized.

Repeat step 4 if you would like to add additional documents to the package. Once you have added all of the documents, select the **View Summary** button to continue.

The screenshot shows the 'e-Dossier V 1.05' application window. The title bar includes the EPA logo and navigation links: Home, Settings, Help, About, and Exit. The breadcrumb trail reads: Home > Package [Chemical D Product Registratio...] > Application [Sec 3 -New] > Documents.

Form fields include:

- Document Group: [Text Box] (Document Group is Optional, Future Use, not Currently used by EPA)
- Contains CBI?: * ☐ Yes ☐ No
- Comments: [Text Box] (Comments are Optional, Future Use, not Currently used by EPA)

Documents: [1]

Document Type	Document#	File Name	Location	Title
Study Profile		Chemical D - study profile.doc	C:\Users\SEAU\Documents\le-dc	

Buttons: Copy Document, Edit Document, Delete Document.

Bottom controls: ☐ Mark for review, Add Document, Cancel, and View Summary (circled in red).

Figure 5-5: Package Document Added

6. The *Package [Title]* screen appears listing the package details, application information, and documents.

If you would like to provide or edit package metadata, follow the steps provided in section 5.3 (Add/Edit Package Metadata). If you would like to provide or edit package level documents, follow the steps provided in section 5.4 (Add/Edit Package Level Documents).

If you would like to provide and/or edit application metadata and documents, follow the steps provided in section 6 (Add, Edit, & Delete Non-EDSP Application Metadata & Documents).

If you would like to finalize the package without adding or editing application metadata and documents, follow the steps provided in section 7 (Validate & Finalize a Non-EDSP Package).

The screenshot shows the 'e-Dossier V1.05' application window. The title bar includes the EPA logo and the text 'U.S. ENVIRONMENTAL PROTECTION AGENCY'. The menu bar contains 'Home', 'Settings', 'Help', 'About', and 'Exit'. The breadcrumb trail is 'Home > Package [Chemical B Product Registratio...]'. The left sidebar shows a tree view with 'Chemical B Product Registratio...' expanded, containing 'EUP-New-1'. The main content area is titled 'Package Details: Add / Edit' and contains the following information:

Package Name : Chemical B Product Registration
Description :
Email : sample@company.com
Is PRIA : No
Contact Profile : Profile 1

Application List:

Name	Application Type	Regulatory Type
EUP-New-1	New Registration	Experimental Use Permit - Section 5

Documents: Add / Edit

Type	Contains CBI?	Name
Submission Cover Letter	No	ABCD Chem Co - Submission cover letter.docx

At the bottom of the main content area are three buttons: 'Add', 'Delete', and 'Validate'.

Figure 5-6: Package [Title] Screen

5.2 Continue a Saved Non-EDSP Package

1. From the *Home* screen, select the **Continue Saved Package** button.

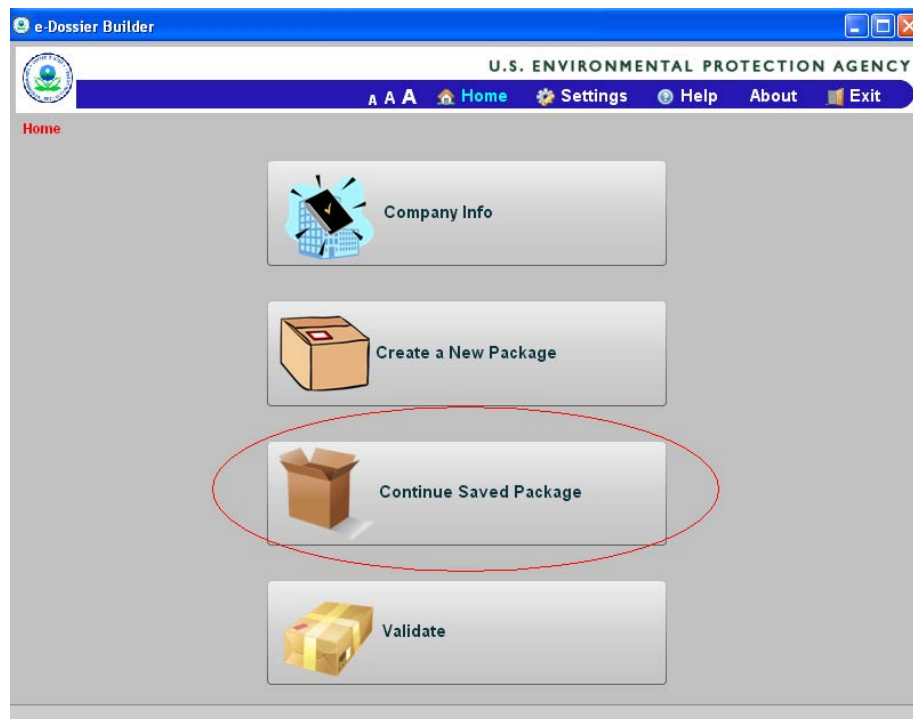


Figure 5-7: Continue Saved Non-EDSP Package

2. The *Open Package* screen appears and provides a listing of all packages. Click on one of the **packages** listed, and then select the **Open** button.

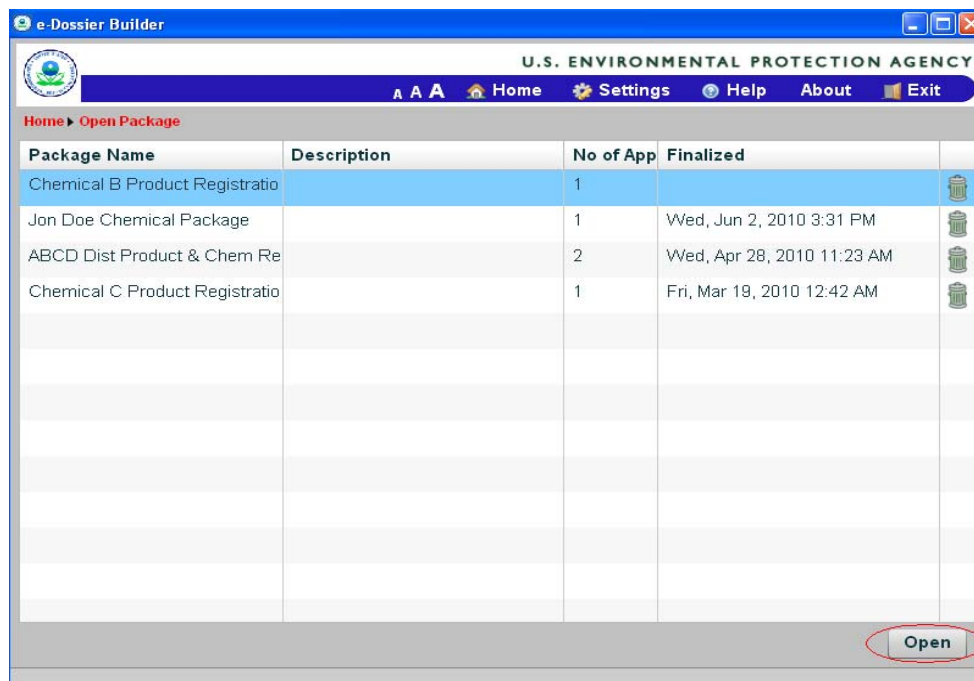


Figure 5-8: Open Package Screen

3. The *Package [Title]* screen appears. Continue with the creation of the package.

U.S. ENVIRONMENTAL PROTECTION AGENCY

Home > Package [Chemical B Product Registratio...]

▼ Chemical B Product Registration

EUP-New-1

Package Details: [Add / Edit](#)

Package Name : Chemical B Product Registration

Description :

Email : sample@company.com

Is PRIA : No

Contact Profile : Profile 1

Application List:

Name	Application Type	Regulatory Type
EUP-New-1	New Registration	Experimental Use Permit - Section 5

Documents: [Add / Edit](#)

Type	Contains CBI?	Name
Submission Cover Letter	No	ABCD Chem Co - Submission cover letter.docx

[Add](#) [Delete](#) [Validate](#)

Figure 5-9: Package [Title] Screen

5.3 Add/Edit Package Metadata

1. From the *Package [Title]* screen, select the **Add/Edit** button provided next to *Package Details*.

eDossier V 1.05

U.S. ENVIRONMENTAL PROTECTION AGENCY

Home Package [Chemical B Product Registratio...]

▼ Chemical B Product Registratio

EUP-New-1

Package Details: **Add / Edit**

Package Name : Chemical B Product Registration

Description :

Email : sample@company.com

Is PRIA : No

Contact Profile : Profile 1

Application List:

Name	Application Type	Regulatory Type
EUP-New-1	New Registration	Experimental Use Permit - Section 5

Documents: **Add / Edit**

Type	Contains CBI?	Name
Submission Cover Letter	No	eDossier Builder User Guide v2.1.docx

Add Delete Validate

Figure 5-10: Package Details Add/Edit

2. The *Package Info* screen appears. Make desired changes, and then select the **View Summary** button to return to the *Package [Title]* screen.

If you would like to provide or edit package documents, select the **Next>** button and go to step 2 of section 5.4 (Add/Edit Package Level Documents).

e-Dossier V 1.05

U.S. ENVIRONMENTAL PROTECTION AGENCY

Home Settings Help About Exit

Home > Package [Chemical B Product Registratio...] > Edit

Package Info

Package Name: Chemical D Product Registration

Description: (Package Description is Optional for internal use by company, not Currently used by EPA)

Is this PRIA? ☐ (Check this if this submission is subject to PRIA Fees)

(PRIA is Optional/Future Use, not Currently used by EPA)

Company Profile: Profile 1

Next > View Summary

Figure 5-11: Edit Package Info

3. The *Package [Title]* screen appears and the changes made are provided in *Package Details*.

The screenshot shows the 'eDossier V1.05' application window. The title bar indicates the U.S. ENVIRONMENTAL PROTECTION AGENCY. The menu bar includes Home, Settings, Help, About, and Exit. The main window is titled 'Home > Package [Chemical D Product Registratio...]'.

On the left, there is a sidebar with a tree view showing 'Chemical D Product Registration' and 'EUP-New-1'.

The main area is divided into two sections:

Package Details: Add / Edit

Package Name : Chemical D Product Registration
Description :
Email : sample@company.com
Is PRIA : No
Contact Profile : Profile 1

Application List:

Name	Application Type	Regulatory Type
EUP-New-1	New Registration	Experimental Use Permit - Section 5

Documents: Add / Edit

Type	Contains CBI?	Name
Submission Cover Letter	No	ABCD Chem Co - Submission cover letter.docx

At the bottom of the main area, there are three buttons: Add, Delete, and Validate.

Figure 5-12: Package Info Change

5.4 Add/Edit Package Level Documents

1. From the *Package [Title]* screen, select the **Add/Edit** button provided next to *Documents*.

The screenshot shows the 'e-Dossier V1.05' application window. The title bar includes the U.S. Environmental Protection Agency logo and navigation links: Home, Settings, Help, About, and Exit. The main content area is titled 'Package [Chemical D Product Registratio...]' and features a left sidebar with a tree view containing 'Chemical D Product Registration' and 'EUP-New-1'. The main panel displays 'Package Details' for 'EUP-New-1' with fields for Package Name, Description, Email, Is PRIA, and Contact Profile. Below this is an 'Application List' table. At the bottom, the 'Documents' section has an 'Add / Edit' button circled in red, followed by a table listing documents.

Name	Application Type	Regulatory Type
EUP-New-1	New Registration	Experimental Use Permit - Section 5

Type	Contains CBI?	Name
Submission Cover Letter	No	ABCD Chem Co - Submission cover letter.docx

Figure 5-13: Package Document Add/Edit

- The *Documents for the Package* screen appears. Add another document or make changes to a previously added document by selecting the document and clicking on the **Edit Document** button. When editing a previously added document, be sure to select the **Save Document** button when finished.

If you would like to delete a document, select the **Delete Document** button.

When complete, select the **View Summary** button.

Note: If adding multiple documents, the last document added will be placed at the bottom of the *Documents* table.

Note, the documents are not officially attached until the package is finalized.

U.S. ENVIRONMENTAL PROTECTION AGENCY

Home > Package [Chemical D Product Registratio...] > Application [Sec 3 -New] > Documents

Document Group: (Document Group is Optional, Future Use, not Currently used by EPA)

Contains CBI? * ☐ Yes ☐ No

Comments: (Comments are Optional, Future Use, not Currently used by EPA)

Documents: [1]

Document Type	Document#	File Name	Location	Title
Study Profile		Chemical D - study profile.doc	C:\Users\SEAU\Documents\le-dc	

Copy Document Edit Document Delete Document

☐ Mark for review Add Document Cancel View Summary

Figure 5-14: Edit Package Document

3. The *Package [Title]* screen appears and the changes made are provided in *Documents*.

The screenshot shows the eDossier V 1.05 application window. The title bar reads "e-Dossier V 1.05". The menu bar includes "Home", "Settings", "Help", "About", and "Exit". The breadcrumb trail is "Home > Package [Chemical D Product Registratio...]". The left sidebar shows a tree view with "Chemical D Product Registration" expanded, containing a sub-item "EUP-New-1". The main content area is divided into three sections:

Package Details: [Add / Edit](#)

Package Name : Chemical D Product Registration
Description :
Email : sample@company.com
Is PRIA : No
Contact Profile : Profile 1

Application List:

Name	Application Type	Regulatory Type
EUP-New-1	New Registration	Experimental Use Permit - Section 5

Documents: [Add / Edit](#)

Type	Contains CBI?	Name
Submission Cover Letter	No	ABCD Chem Co - Submission cover letter.docx

At the bottom of the main content area are three buttons: "Add", "Delete", and "Validate".

Figure 5-15: Package [Title] Screen

5.5 Open Package Level Documents

Note: This can only be completed if you have attached documents to the package.

1. From the *Package [Title]* screen, click on a **document name** provided in the *Documents* table.

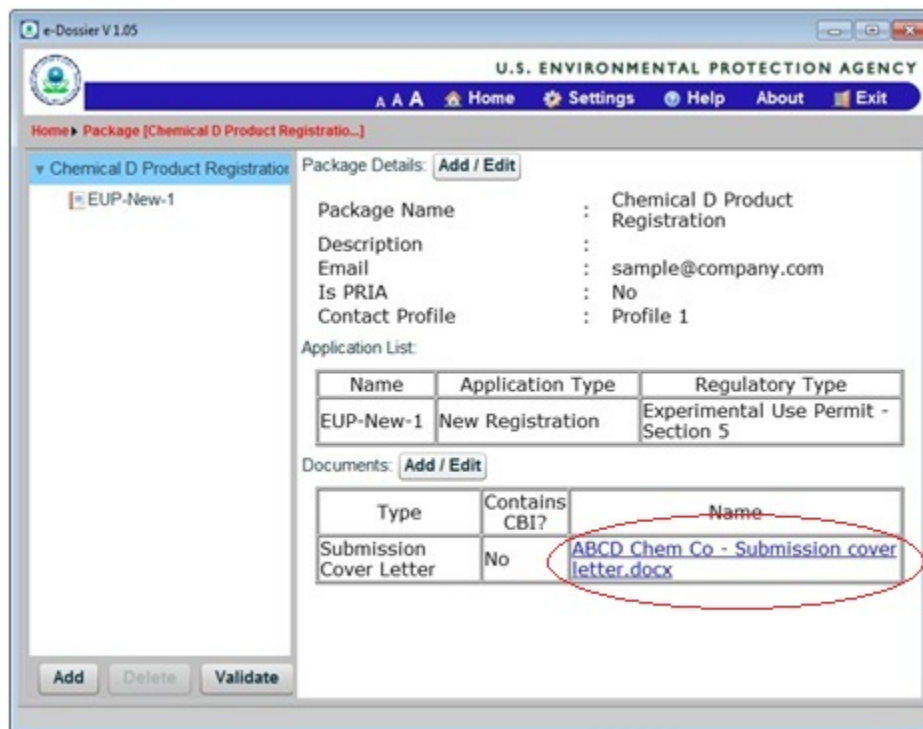


Figure 5-16: Select Package Document

2. The *File Download* window appears. Select the **Open** button.

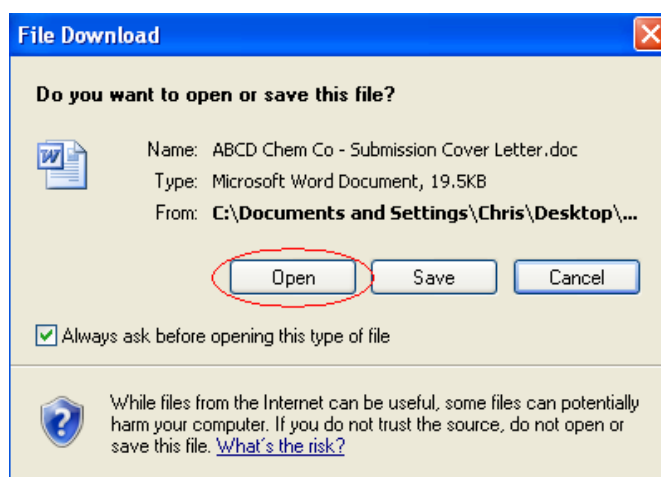


Figure 5-17: File Download Window

3. The document opens in Internet Explorer as demonstrated below.

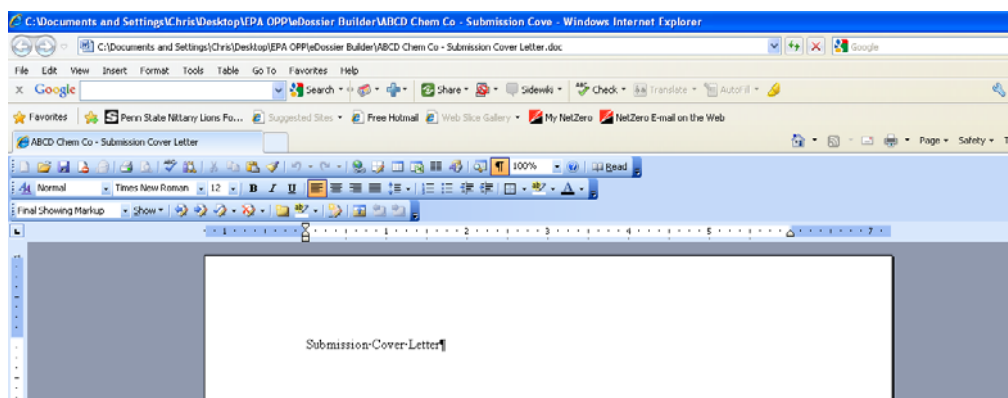


Figure 5-18: Package Level Document

5.6 Delete a Package

1. From the *Home* screen, select the **Continue Saved Package** button.

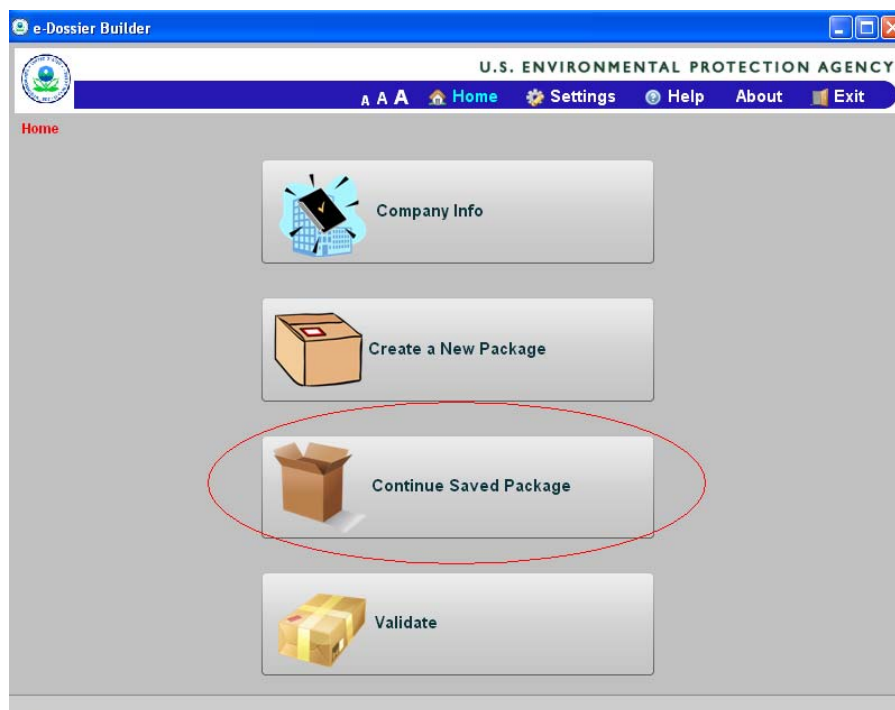


Figure 5-19: Continue Saved Package

- The *Open Package* screen appears. Select the **Delete (trash can)** button for the package you would like to delete on the right side of the screen.

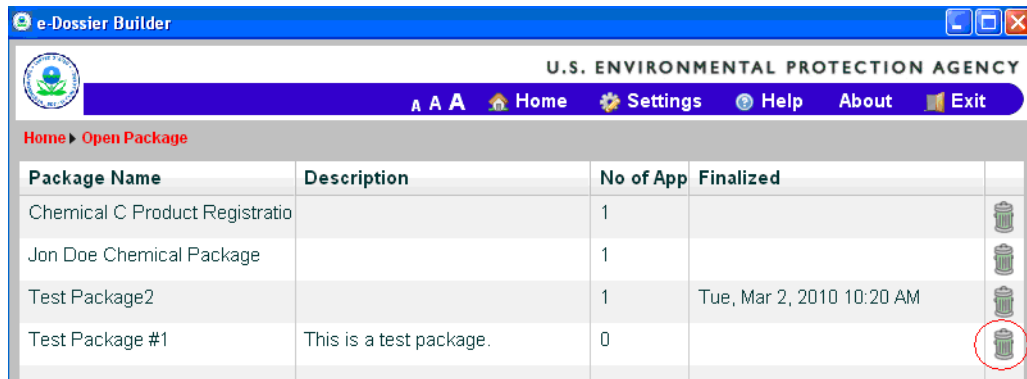


Figure 5-20: Package Deletion

- The *Delete* window appears asking if you would like to delete the package. Select the **Yes** button.

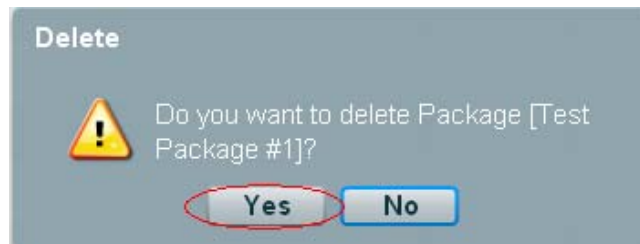


Figure 5-21: Delete Window

- The *Open Package* screen refreshes and the deleted package is no longer provided.

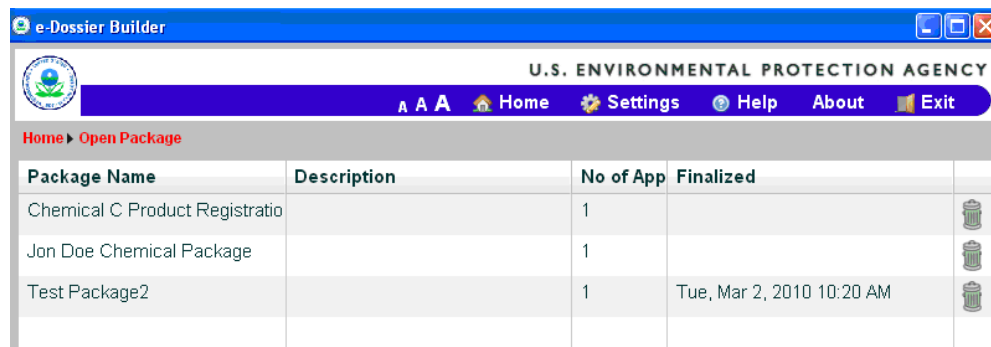


Figure 5-22: Package Deleted

6 Add, Edit, & Delete Non-EDSP Application Metadata & Documents

6.1 Provide an Application Title

1. From the *Package [Title]* screen, click on one of the **Application Types** listed in the tree view on the left side of the screen.

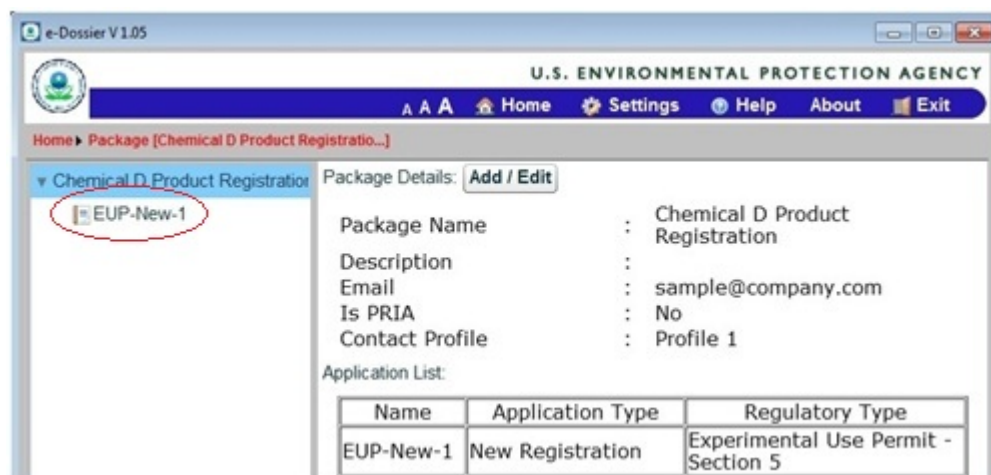


Figure 6-1: Application Type Selection

2. The Application Type details, metadata, and documents appear on the right side of the screen as shown below. Select the **Add/Edit** button provided next to *Application Details*.

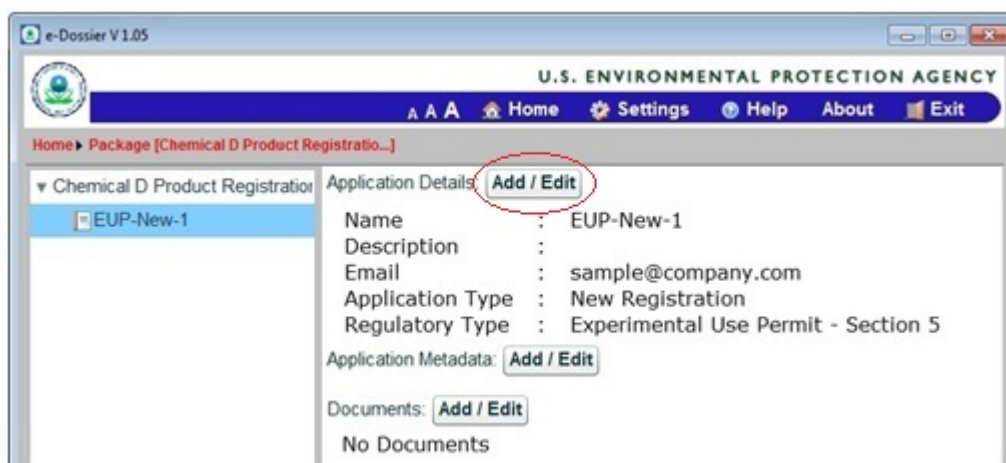


Figure 6-2: Application Details Add/Edit

3. The *Application Information* screen appears. Enter a **new name** inside the *Application Name* field, and then select the **View Summary** button.

If you would like to provide or edit the Application Metadata, select the **Next>** button and go to step 2 of section 6.2 (Add/Edit Application Metadata) to continue.

e-Dossier V 1.05

U.S. ENVIRONMENTAL PROTECTION AGENCY

Home > Package [Chemical B Product Registratio...] > Application [EUP-New-1] > Edit

Application Information

Application Name: EUP New Registration

Description: (Description is Optional, for internal use by company, not Currently used by EPA)

Email: sample@company.com

Next > View Summary

Figure 6-3: Application Information

4. The *Package [Title]* screen appears and the *Application Name* is changed to the name entered in step 3.

e-Dossier V 1.05

U.S. ENVIRONMENTAL PROTECTION AGENCY

Home > Package [Chemical B Product Registratio...]

Chemical B Product Registratio...

EUP New Registration

Application Details: Add / Edit

Name: EUP New Registration

Description:

Email: sample@company.com

Application Type: New Registration

Regulatory Type: Experimental Use Permit - Section 5

Application Metadata: Add / Edit

Documents: Add / Edit

No Documents

Figure 6-4: Application Name Change

6.2 Add/Edit Application Metadata

1. From the *Package [Title]* screen and the Application selected, click on the **Add/Edit** button provided next to *Application Metadata*.

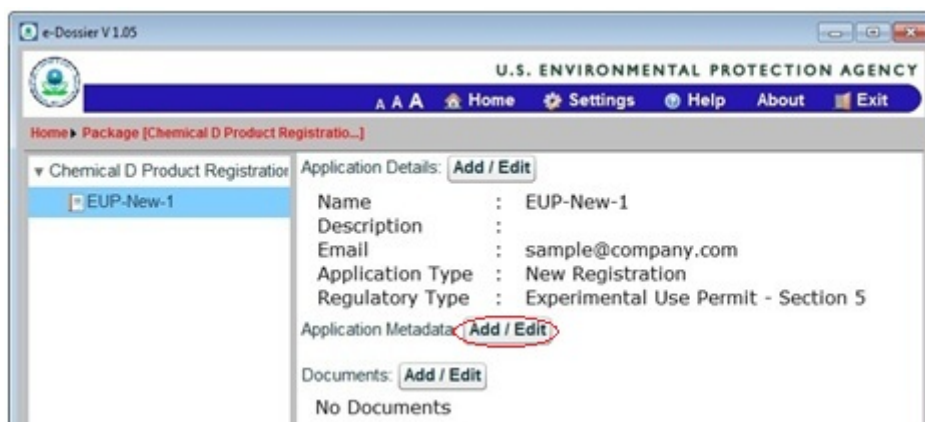


Figure 6-5: Application Metadata Add/Edit

2. The *Application Metadata* screen appears. Complete all **required fields** (*) and any of the other fields as necessary. If you would like to return to this screen later, select the **Mark for review** box provided on bottom left side of the screen.

Select the **View Summary** button to return to the *Package [Title]* screen.

If you would like to provide or edit the Application Documents, select the **Next>** button and go to step 2 of section 6.3 (Add/Edit Application Level Documents) to continue.

Figure 6-6: Application Metadata Screen

- The *Package [Title]* screen appears and the *Application Metadata* information is updated with the information entered in step 2.

The screenshot shows the 'e-Dossier V 1.05' application window. The title bar includes the EPA logo and navigation links: Home, Settings, Help, About, and Exit. The breadcrumb trail reads: Home > Package [Chemical B Product Registratio...] > Application [EUP New Registration] > Experimental Use Permit - Section 5. The left sidebar shows a tree view with 'Chemical B Product Registration' expanded, containing 'EUP New Registration'. The main content area is divided into two sections: 'Application Details' and 'Application Metadata'. The 'Application Details' section has an 'Add / Edit' button and lists: Name: EUP New Registration, Description: (empty), Email: sample@company.com, Application Type: New Registration, and Regulatory Type: Experimental Use Permit - Section 5. The 'Application Metadata' section also has an 'Add / Edit' button and lists: InitialSubmission: Yes, AdminNumber: 017289, RiskManager: 07, and Description: (empty). Below these is a 'Documents' section with an 'Add / Edit' button and the text 'No Documents'.

Figure 6-7: Application Metadata Added

- On the *Application Metadata* screen. If you would like to return to this screen later, select the **Mark for review** box provided on bottom left side of the screen. Select 'View Summary' button to go to *Package[Title]* screen.

The screenshot shows the 'Experimental Use Permit - Section 5' screen. The breadcrumb trail is: Home > Package [Chemical B Product Registratio...] > Application [EUP New Registration] > Experimental Use Permit - Section 5. The form contains the following fields: 'Regulatory Type' (Experimental Use Permit - Section 5), 'Application Type' (New Registration), 'Product/Risk Manager' (07), 'Admin Number' (017289), 'Is this an initial submission?' (radio buttons for Yes and No, with 'Yes' selected), and 'Description/Remarks' (a text area). A note below the text area states: '(Description/Remarks is Optional, Future Use, not Currently used by EPA)'. At the bottom left, there is a checkbox labeled 'Mark for review' which is circled in red. At the bottom right, there are two buttons: 'Next >' and 'View Summary'.

Figure 6-8: Application Metadata Mark for Review

5. The *Package [Title]* screen appears and the *Application Metadata* information is updated with ‘*This section is marked for Review’. Select the **Validate** button to go to the *Validate* screen.

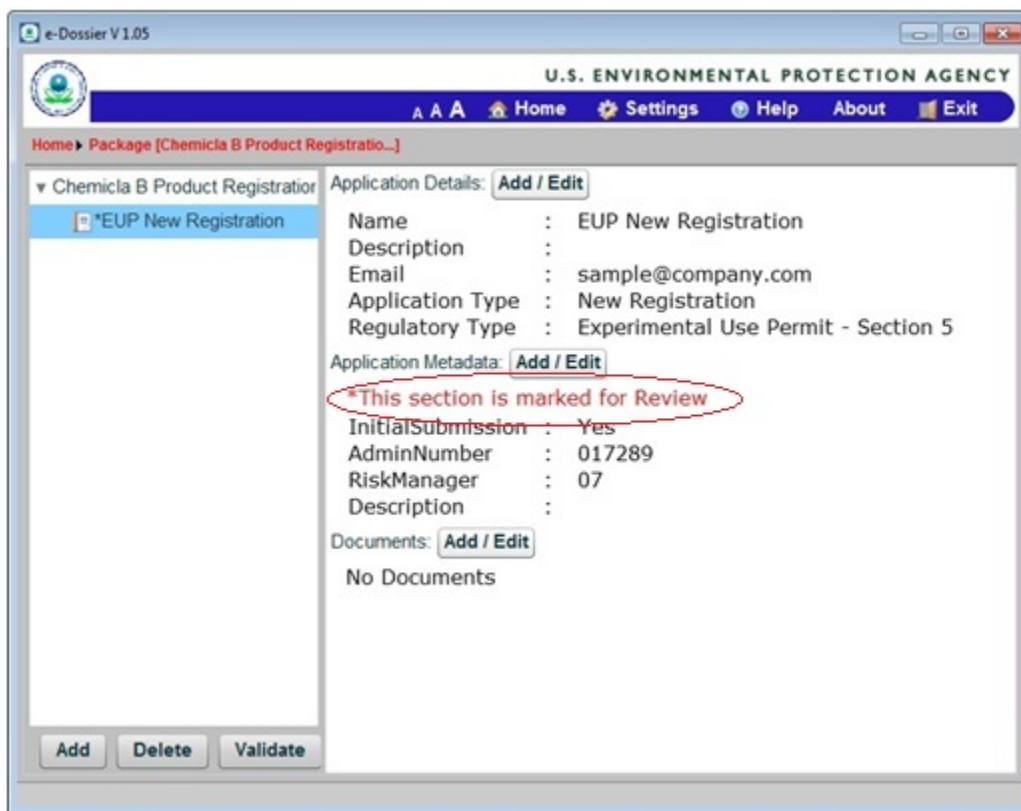


Figure 6-9: Application Metadata Marked for Review

- The *Validate* screen a message stating '*Application [Title] has been marked for review*'. Click '**Review**' button to review the application and '**Finalize**' button to finalize the package.

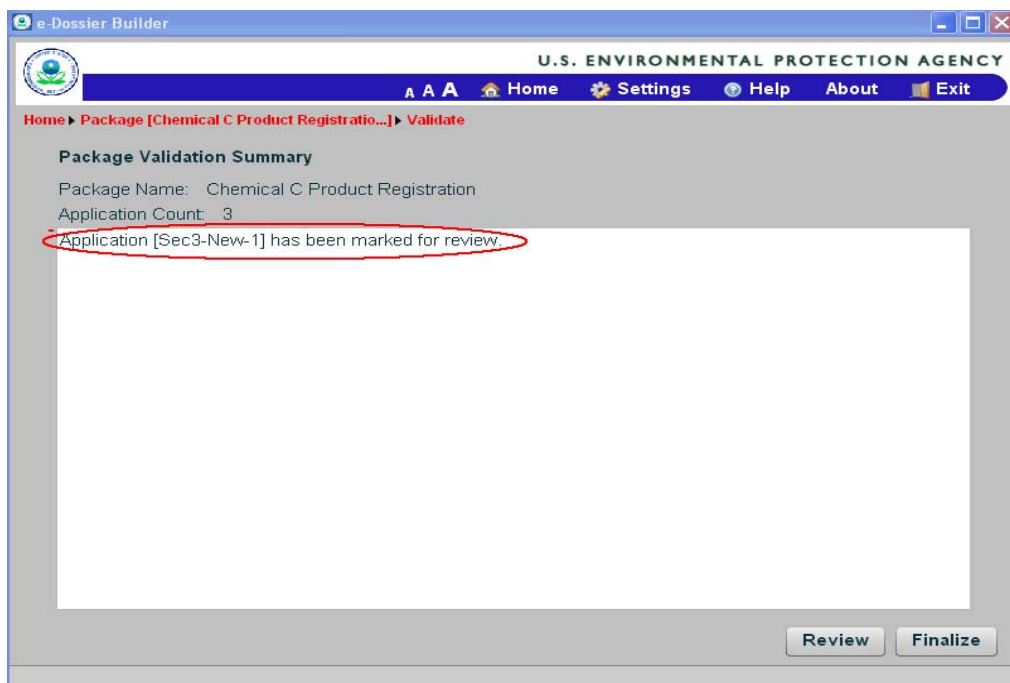


Figure 6-10: Marked for Review

6.3 Add/Edit Application Level Documents

- From the *Package [Title]* screen and the Application selected, click on the **Add/Edit** button provided next to *Documents*.

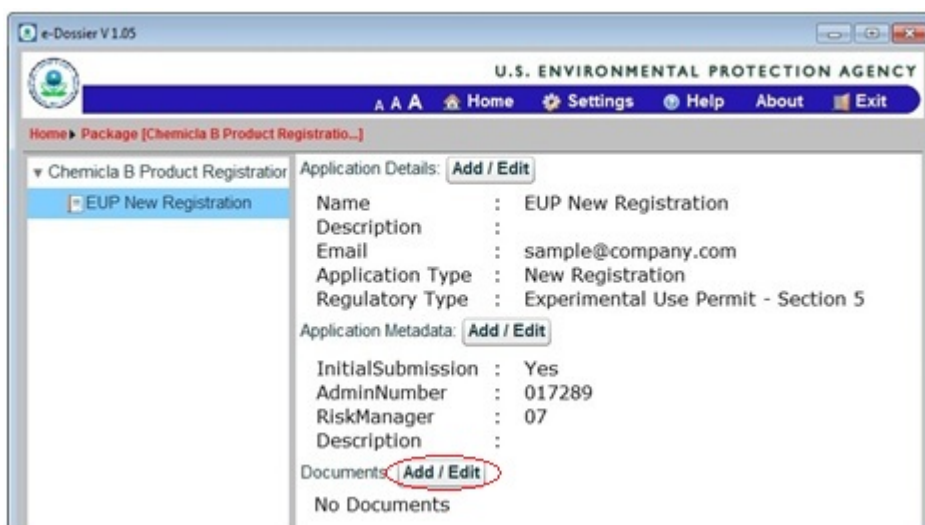


Figure 6-11: Application Documents Add/Edit

2. The *Documents for the Application* screen appears.

If adding a new document, complete all **required fields** (*) and any of the other fields as necessary. If you would like to return to this screen later, select the **Mark for review** box provided on bottom left side of the screen. When complete, select the **Add Document** button.

If you would like to make changes to a previously added document, select the document and click on the **Edit Document** button. When finished, be sure to select the **Save Document** button when finished.

If you would like to delete a document, select the document and click on the **Delete Document** button.

Figure 6-12: Add Application Document

- If you added or edited a document, the document information is provided in the *Documents* table as shown below. If you deleted a document, it is no longer listed in the *Documents* table.

Repeat step 2 if you would like to add additional documents to the application.

Note: If adding multiple documents, the last document added will be placed at the bottom of the *Documents* table. Additionally, documents are not officially attached until the package is finalized.

Once you have added or edited documents, select the **View Summary** button to continue.

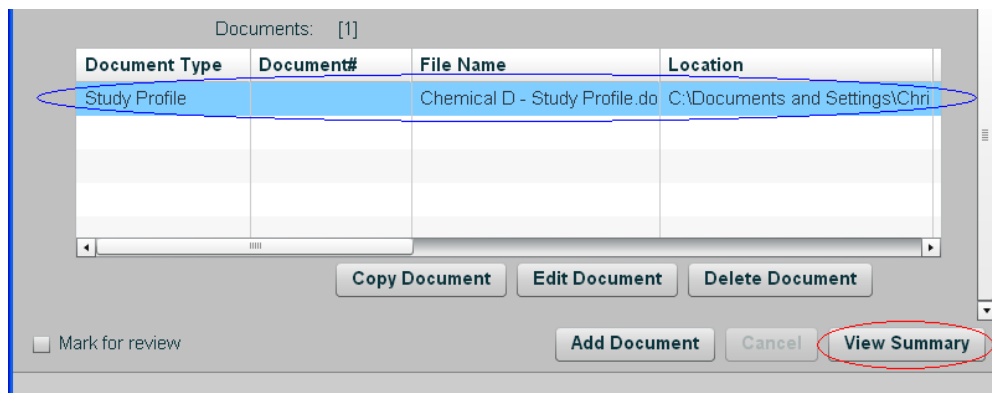


Figure 6-13: Application Document Added

- The *Package [Title]* screen appears and the document information provided in step 2 is listed under *Documents*.

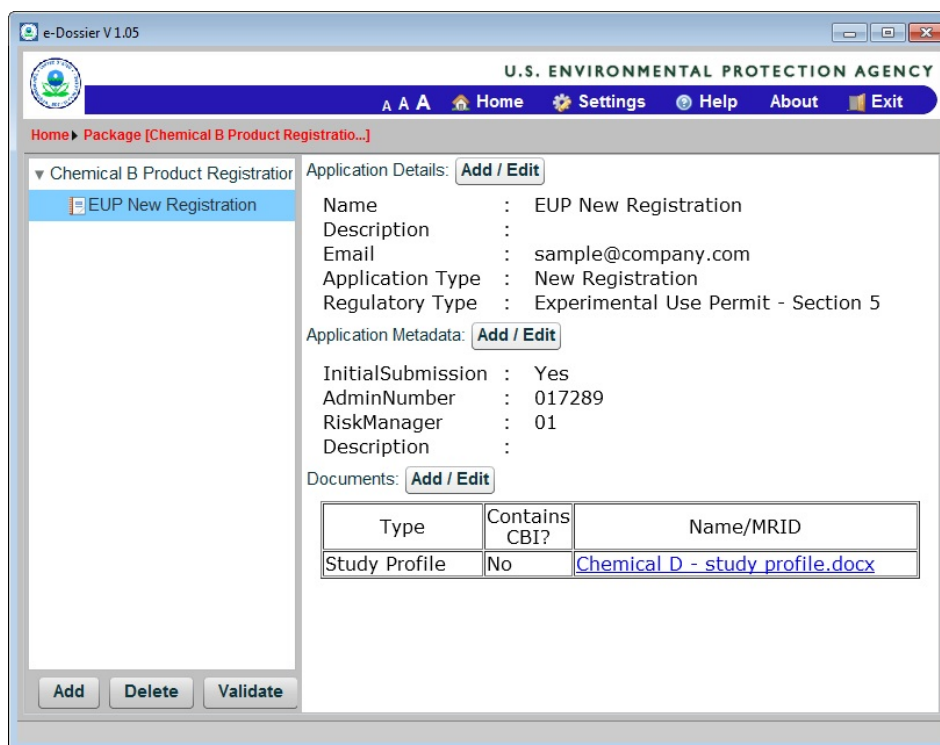


Figure 6-14: Package [Title] Screen

5. On the *Document Metadata* screen. If you would like to return to this screen later, select the **Mark for review** box provided on bottom left side of the screen. Select 'View Summary' button to go to *Package[Title]* screen.

e-Dossier V 1.05

U.S. ENVIRONMENTAL PROTECTION AGENCY

Home > Package [Chemical B Product Registratio...] > Application [EUP New Registration] > Documents

Document Group (Document Group is Optional, Future Use, not Currently used by EPA)

Contains CBI? * ☐ Yes ☐ No

Comments (Comments are Optional, Future Use, not Currently used by EPA)

Documents: [1]

Document Type	Document#	File Name	Location	Title
Study Profile		Chemical D - study profile.doc	C:\Users\SEAU\Documents\le-dc	

Copy Document Edit Document Delete Document

☒ Mark for review Add Document Cancel View Summary

Figure 6-15: Document Metadata Marked for Review

6. The *Package [Title]* screen appears and the *Documents* information is updated with ‘*This section is marked for Review’. Select the **Validate** button to go to the *Validate* screen.

The screenshot shows the eDossier V 1.05 application window. The title bar reads 'e-Dossier V 1.05'. The menu bar includes 'Home', 'Settings', 'Help', 'About', and 'Exit'. The breadcrumb trail is 'Home > Package [Chemical B Product Registratio...]'. The left sidebar shows 'Chemical B Product Registratio...' with a sub-item '*EUP New Registration'. The main content area is divided into three sections: 'Application Details' with fields for Name, Description, Email, Application Type, and Regulatory Type; 'Application Metadata' with fields for InitialSubmission, AdminNumber, RiskManager, and Description; and 'Documents' with a table. A red oval highlights the text '*This section is marked for Review' above the 'Documents' table.

Type	Contains CBI?	Name/MRID
Study Profile	No	Chemical D - study profile.docx

At the bottom of the window are buttons for 'Add', 'Delete', and 'Validate'.

Figure 6-16: Document Metadata Marked for Review

- The *Validate* screens a message stating '*Application [Title] has been marked for review*'. Click '**Review**' button to review the application and '**Finalize**' button to finalize the package.

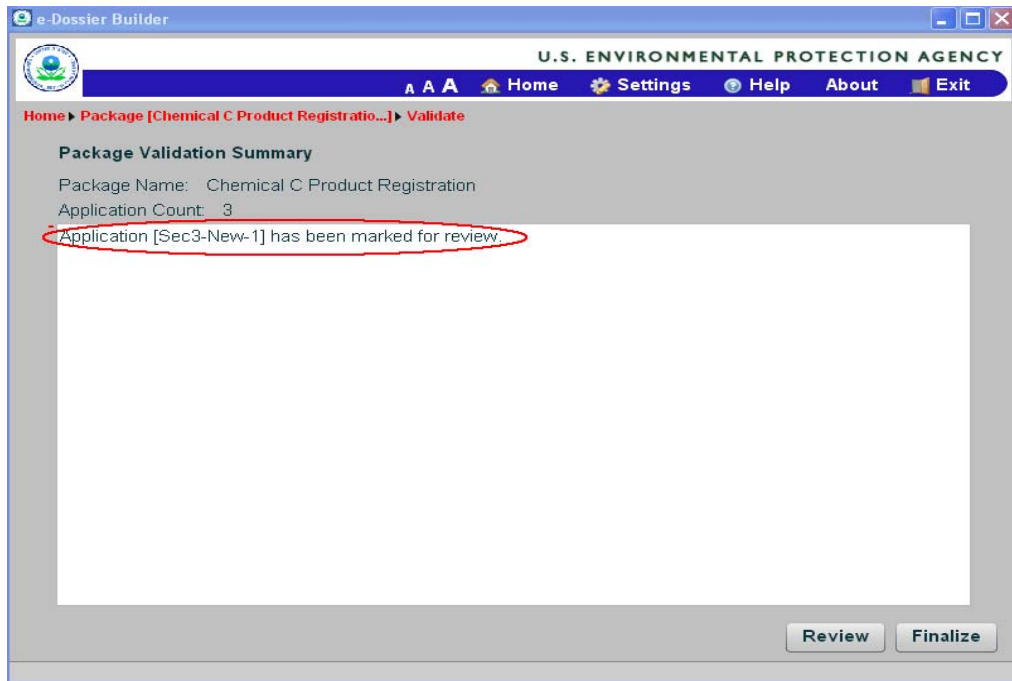


Figure 6-17: Marked for Review

- Once all applications, metadata, and documents have been added, the package can be finalized following the steps provided in section 7 (Validate & Finalize a Non-EDSP Package).

6.4 Open Application Level Documents

Note: This can only be completed if you have attached documents to an application.

1. From the *Package [Title]* screen and an Application selected, click on a **document name** provided in the *Documents* table.

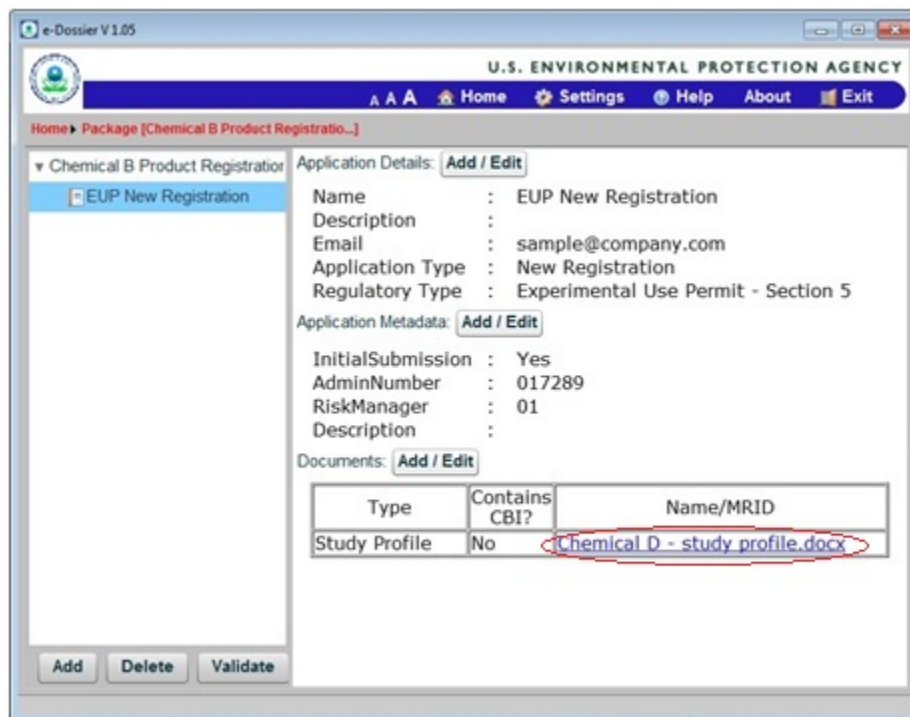


Figure 6-18: Select Application Document for Opening

2. The *File Download* window appears. Select the **Open** button.

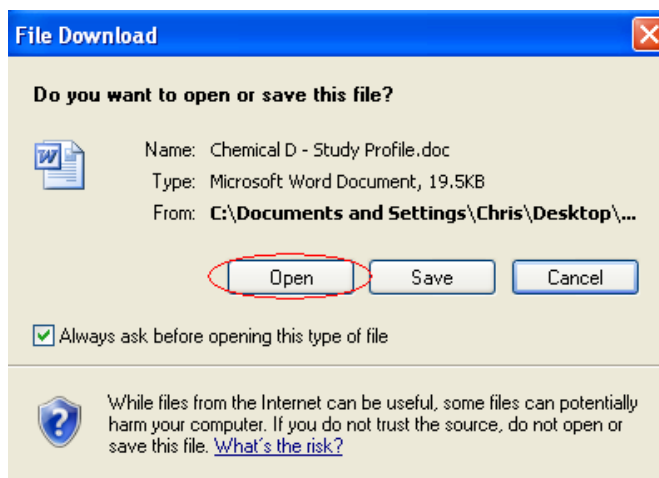


Figure 6-19: File Download Window

- The document opens in Internet Explorer as demonstrated below.

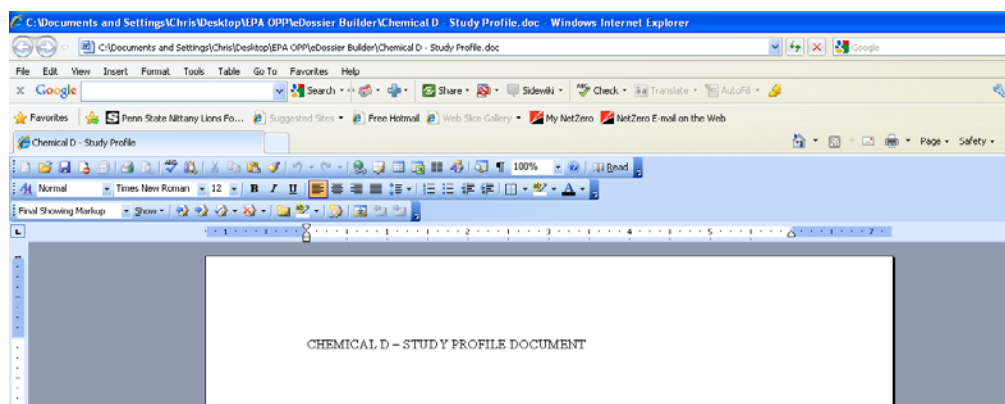


Figure 6-20: Application Level Document

6.5 Add an Application

- From the Package [Title] screen, click on one of the applications listed in the tree view provided on the left side of the screen or select the Package name on left side of the screen, and then select the Add button.

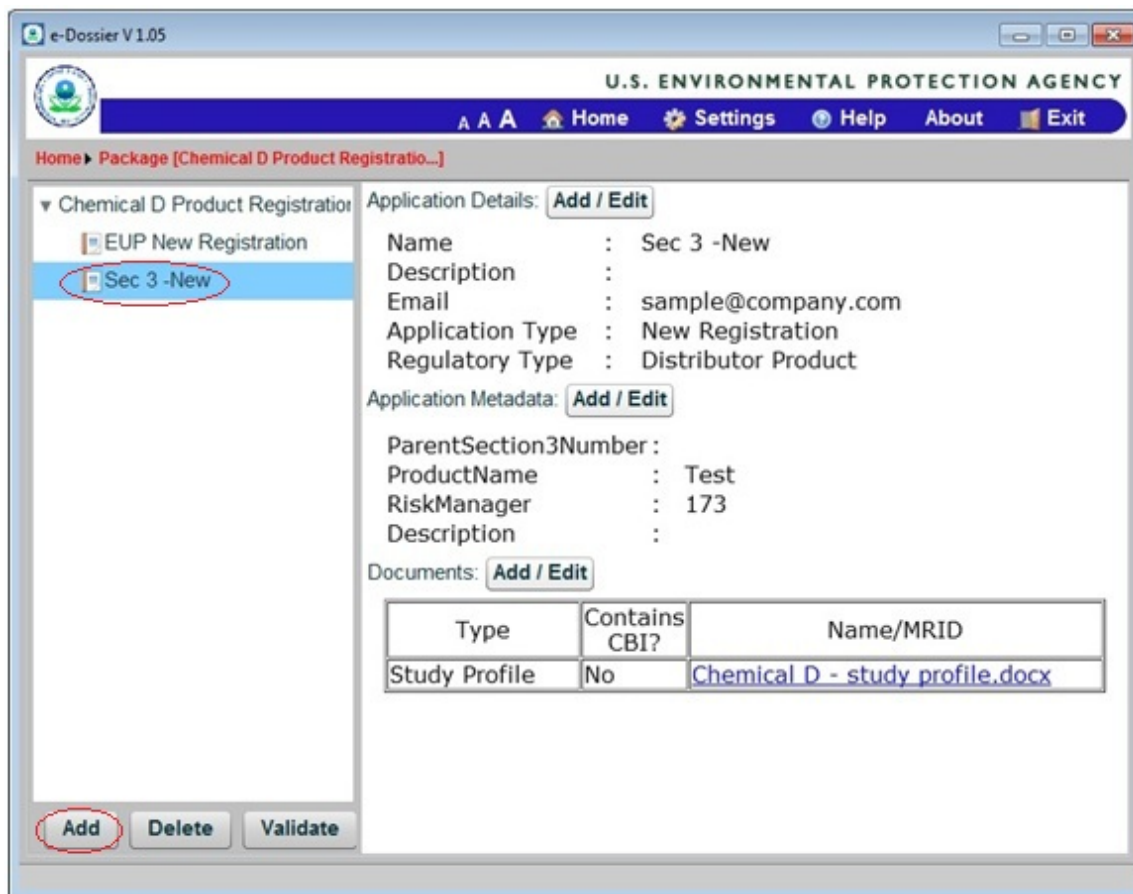


Figure 6-21: Add Application

2. The *New Application* screen appears. Complete all required fields (*) and any other fields as necessary. Select suitable '**Application Type**' and '**Regulatory Type**' from the drop down menu. Select the 'Next >' button and go to '**Application Metadata**' screen.

e-Dossier V 1.05

U.S. ENVIRONMENTAL PROTECTION AGENCY

Home Settings Help About Exit

Home > Package [Chemical D Product Registratio...] > New Application

Application Information

Application Name *

Description (Description is Optional, for internal use by company, not Currently used by EPA)

Email

Application Type

Regulatory Type

Next >

Figure 6-22: Add Application

3. The *Application Metadata* screen appears. Complete all **required fields** (*) and any of the other fields as necessary. If you would like to return to this screen later, select the **Mark for review** box provided on bottom left side of the screen.

Select the **View Summary** button to return to the *Package [Title]* screen.

If you would like to provide or edit the Application Documents, select the **Next>** button and go to 'Documents for Application' screen.

e-Dossier V 1.05

U.S. ENVIRONMENTAL PROTECTION AGENCY

Home Settings Help About Exit

Home > Package [Chemical D Product Registratio...] > Application [Test Spray] > Experimental Use Permit - Section 5

Experimental Use Permit - Section 5

Regulatory Type: Experimental Use Permit - Section 5

Application Type: New Registration

Product/Risk Manager: 07

Admin Number: 017289

Is this an initial submission? ☒ Yes ☐ No

Description/Remarks: (Description/Remarks is Optional, Future Use, not Currently used by EPA)

☐ Mark for review

Next > View Summary

Figure 6-23: Add Application

4. The *Documents for the Application* screen appears.

If adding a new document, complete all **required fields** (*) and any of the other fields as necessary. If you would like to return to this screen later, select the **Mark for review** box provided on bottom left side of the screen. When complete, select the **Add Document** button.

If you would like to make changes to a previously added document, select the document and click on the **Edit Document** button. When finished, be sure to select the **Save Document** button when finished.

If you would like to delete a document, select the document and click on the **Delete Document** button.

Figure 6-24: Application Level Document

5. The *Documents Metadata* screen appears. Complete all **required fields** (*) and any of the other fields as necessary. If you would like to return to this screen later, select the **Mark for review** box provided on bottom left side of the screen.

Select the **View Summary** button to return to the *Package [Title]* screen.

U.S. ENVIRONMENTAL PROTECTION AGENCY

Home > Package [Chemical D Product Registratio...] > Application [Test Spray] > Documents

Document Group (Document Group is Optional, Future Use, not Currently used by EPA)

Contains CBI? * ☐ Yes ☐ No

Comments (Comments are Optional, Future Use, not Currently used by EPA)

Documents: [1]

Document Type	Document#	File Name	Location	Title
Study Profile		Chemical D - study profile.doc	C:\Users\SEAU\Documents\le-dc	

Copy Document Edit Document Delete Document

☐ Mark for review

Add Document Cancel View Summary

Figure 6-25: Application Level Document

6. The *Package [Title]* screen displays the new application added to the package.

The screenshot shows the eDossier V1.05 application window. The title bar reads 'e-Dossier V1.05'. The menu bar includes 'Home', 'Settings', 'Help', 'About', and 'Exit'. The main content area is titled 'Package [Chemical D Product Registratio...]' and features a left sidebar with a tree view under 'Chemical D Product Registration' containing 'EUP New Registration', 'Sec 3 -New', and 'Test Spray'. The 'Test Spray' item is selected. The main panel displays 'Application Details' and 'Application Metadata' for the selected item. The 'Application Details' section includes fields for Name, Description, Email, Application Type, and Regulatory Type. The 'Application Metadata' section includes fields for InitialSubmission, AdminNumber, RiskManager, and Description. Below these sections is a 'Documents' table with columns for Type, Contains CBI?, and Name/MRID. The table contains one row for 'Study Profile'. At the bottom of the window are 'Add', 'Delete', and 'Validate' buttons.

U.S. ENVIRONMENTAL PROTECTION AGENCY

Home Package [Chemical D Product Registratio...]

Chemical D Product Registration

- EUP New Registration
- Sec 3 -New
- Test Spray

Application Details: [Add / Edit](#)

Name : Test Spray

Description :

Email : sample@company.com

Application Type : New Registration

Regulatory Type : Experimental Use Permit - Section 5

Application Metadata: [Add / Edit](#)

InitialSubmission : Yes

AdminNumber : 017289

RiskManager : 07

Description :

Documents: [Add / Edit](#)

Type	Contains CBI?	Name/MRID
Study Profile	No	Chemical D - study profile.docx

[Add](#) [Delete](#) [Validate](#)

Figure 6-26: Package Summary

6.6 Delete an Application

1. From the *Package [Title]* screen, click on one of the **applications** listed in the tree view provided on the left side of the screen, and then select the **Delete** button.

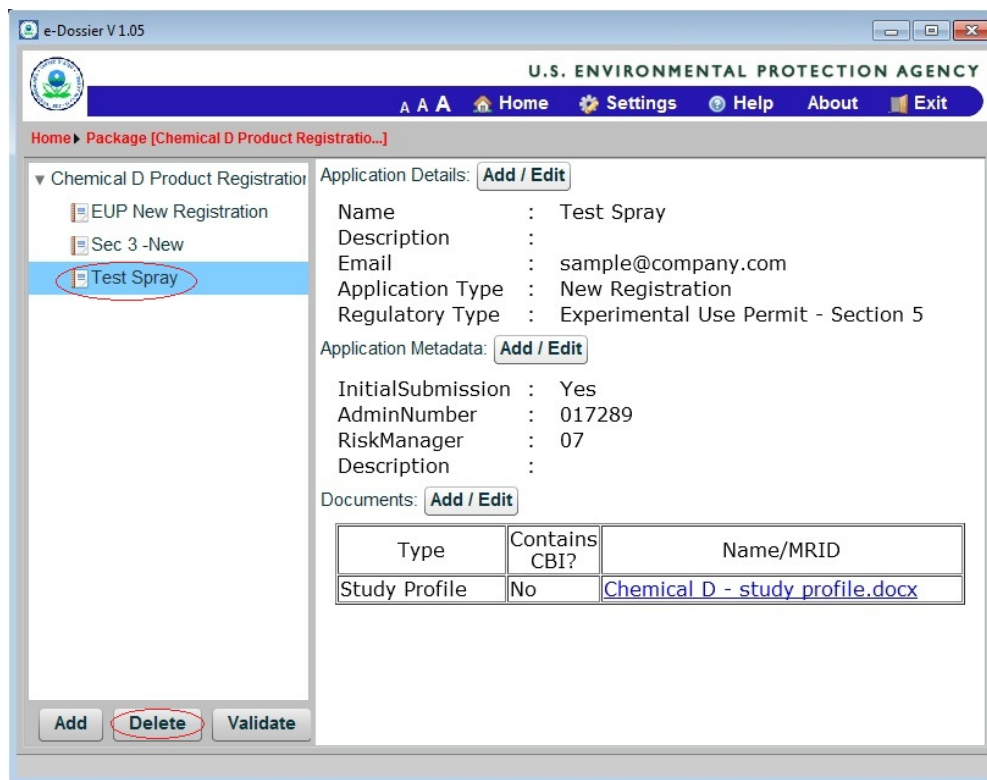


Figure 6-27: Application Selection & Deletion

2. The *Delete* window appears asking if you would like to delete the application. Select the **Yes** button.



Figure 6-28: Delete Window

3. The *Package [Title]* window appears and the application selected for deletion is no longer provided.

The screenshot shows the 'e-Dossier V1.05' application window. The title bar includes the text 'e-Dossier V1.05' and standard window controls. The main window has a header with the U.S. Environmental Protection Agency logo and navigation links: 'Home', 'Settings', 'Help', 'About', and 'Exit'. Below the header, a breadcrumb trail reads 'Home > Package [Chemical D Product Registration...]'. The left sidebar shows a tree view with 'Chemical D Product Registration' expanded, containing 'EUP New Registration' and 'Sec 3 -New'. The main content area is divided into three sections: 'Application Details' with fields for Name, Description, Email, Application Type, and Regulatory Type; 'Application Metadata' with fields for ParentSection3Number, ProductName, RiskManager, and Description; and 'Documents' with a table listing documents. At the bottom of the window are 'Add', 'Delete', and 'Validate' buttons.

Application Details: [Add / Edit](#)

Name : Sec 3 -New
Description :
Email : sample@company.com
Application Type : New Registration
Regulatory Type : Distributor Product

Application Metadata: [Add / Edit](#)

ParentSection3Number :
ProductName : Test
RiskManager : 173
Description :

Documents: [Add / Edit](#)

Type	Contains CBI?	Name/MRID
Study Profile	No	Chemical D - study_profile.docx

[Add](#) [Delete](#) [Validate](#)

Figure 6-29: Application Deleted

7 Validate & Finalize a Non-EDSP Package

1. From the *Package [Title]* screen, select the **Validate** button.

The screenshot shows the e-Dossier V 1.05 application window. The title bar reads 'e-Dossier V 1.05'. The menu bar includes 'Home', 'Settings', 'Help', 'About', and 'Exit'. The main content area is titled 'Package [Chemical D Product Registratio...]' and contains a left sidebar with a tree view showing 'Chemical D Product Registration' expanded, with sub-items 'EUP New Registration' and 'Sec 3 -New'. The main panel displays application details for 'Test Spray', including description, email, application type, and regulatory type. It also shows application metadata and a table of documents. The 'Validate' button at the bottom is circled in red.

U.S. ENVIRONMENTAL PROTECTION AGENCY

Home Package [Chemical D Product Registratio...]

Chemical D Product Registration

EUP New Registration

Sec 3 -New

Application Details: Add / Edit

Name : Test Spray

Description :

Email : sample@company.com

Application Type : New Registration

Regulatory Type : Experimental Use Permit - Section 5

Application Metadata: Add / Edit

InitialSubmission : Yes

AdminNumber : 017289

RiskManager : 07

Description :

Documents: Add / Edit

Type	Contains CBI?	Name/MRID
Study Profile	No	Chemical D - study profile.docx

Add Delete **Validate**

Figure 7-1: Package Validate Button

2. The *Package Validation Summary* screen appears.

If you marked a previous application screen for review, or if errors are found, these are listed on the screen. If so, correct the errors identified and/or review the application screens marked for review.

If not, a message appears stating “The package has been processed successfully.” Select the **Finalize** button.

Note: Once a package is finalized, it can no longer be edited. The package can be ‘Reviewed’ before finalizing the package.

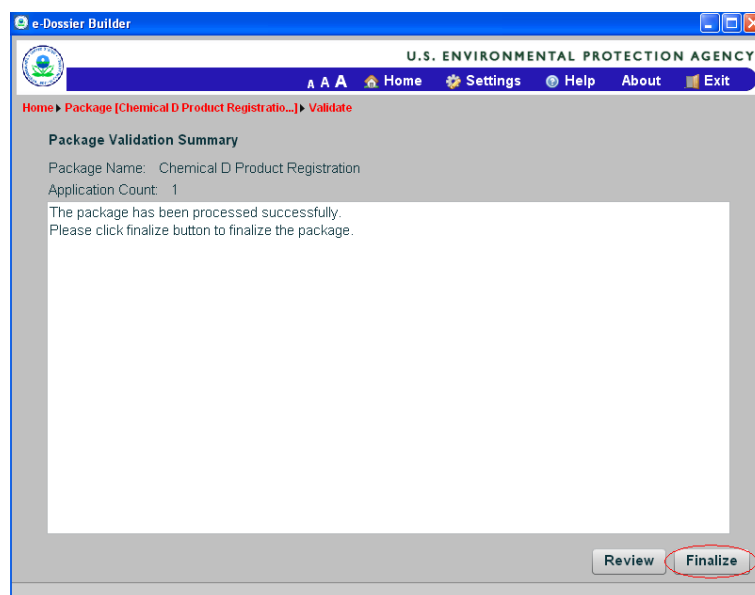


Figure 7-2: Package Validation Summary

3. The *Package Creation Successful* screen appears. If you would like to open the package storage location, select the **Open the contain folder** check box, and then select the **OK** button. If not, just select the **OK** button.

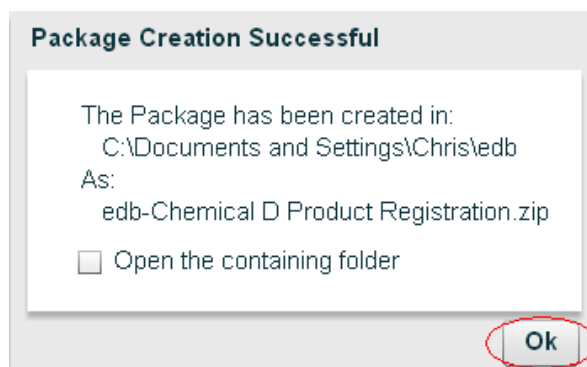


Figure 7-3: Package Creation Successful

4. Once the package has been created, it is now ready to be submitted to EPA. Directions for submitting the package can be found at the EPA OPP electronic submission Web site.

8 Create, Edit, and Delete an EDSP Package

8.1 Create an EDSP Package

1. From the *Home* screen, select the **Create a New Package** button.

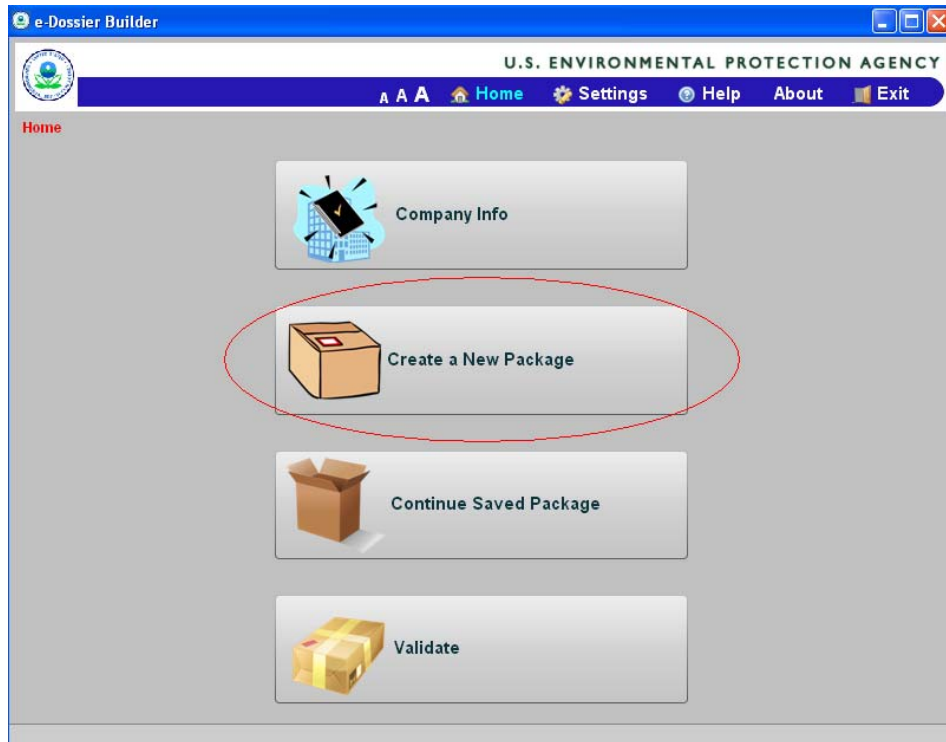


Figure 8-1: Create a New Package

2. The *Confirmation Page* appears. Click on the **No** button for creating a **Non-EDSP package**.

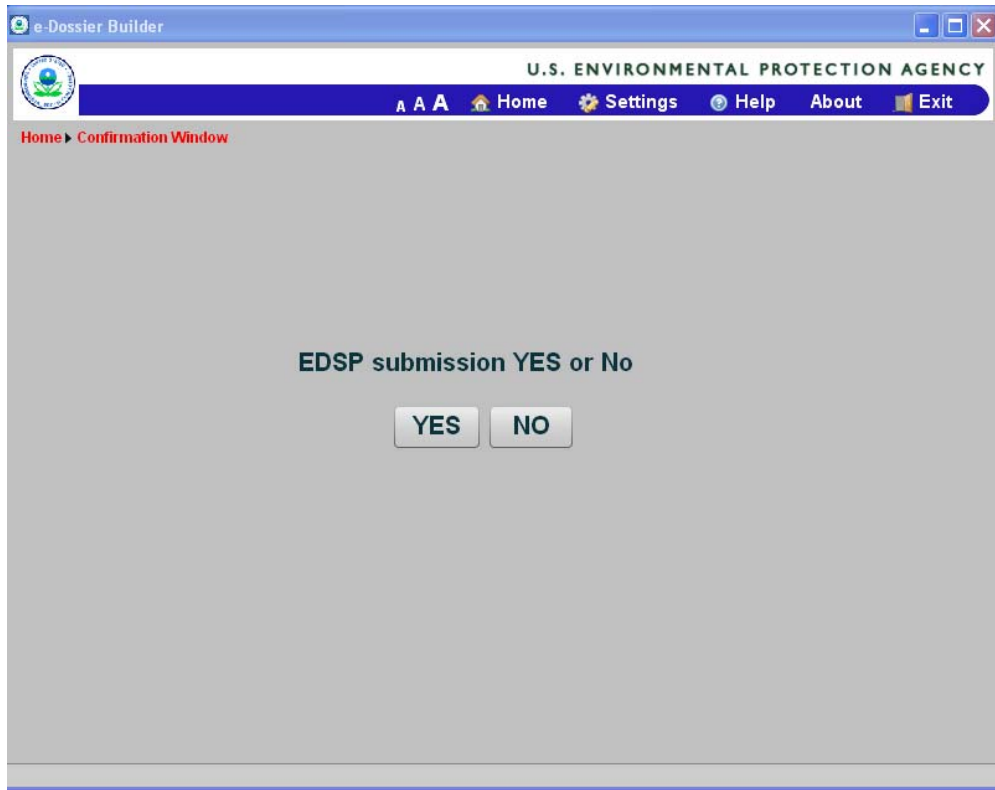


Figure 8-2: Create a EDSP Package Yes or No

3. The *New EDSP Package* screen appears. Complete all **required fields** (*) and any of the other fields as necessary, and then select the **Next>** button.

e-Dossier V 1.05

U.S. ENVIRONMENTAL PROTECTION AGENCY

Home Settings Help About Exit

Home ► New EDSP Package

Package Info

Select the Submission Type *

Order Number *

Package Name

Company Profile *

Description (Package Description is Optional, for internal use by company, not Currently used by EF)

Next >

Figure 8-3: Package Info

4. The *Document for the Package* screen appears. Complete all **required fields (*)** and any of the other fields as necessary, and then select the **Add Document** button.

e-Dossier V 1.05

U.S. ENVIRONMENTAL PROTECTION AGENCY

Home >> [EDSP Package] > Documents

Documents for the Package

Package Name EDSP Order 011001

Order Number EDSP-011001-845

Document Type * Please select an item ...

Document Location * Browse ...

Company Document Number

Document Title

Document Author (Use comma as separator)

Document Date *

Document Group (Document Group is Optional, Future Use, not Currently used by EPA)

Contains CBI? * Yes No

Guideline Number * 890.1100-Amphibian Metamorphosis 890.1150-Androgen Receptor Binding

Mark for review

Add Document Cancel View Summary

Figure 8-4: Add Package Document

5. The document information is provided in the *Documents* table as shown below.

Note:

- When adding multiple documents, the last document added will be placed at the bottom of the *Documents* table.
- Documents are not officially attached until the package is finalized.

Repeat step 6 if you would like to add additional documents to the package. Once you have added all of the documents, select the **View Summary** button to continue.

U.S. ENVIRONMENTAL PROTECTION AGENCY

Home >>[EDSP Package]> Documents

Company Document Number

Document Title

Document Author (Use comma as separator)

Document Date *

Document Group (Document Group is Optional, Future Use, not Currently used by EPA)

Contains CBI? * ☐ Yes ☐ No

Guideline Number * >>"/>

*Use Shift button to select multiple Guideline numbers

Documents: [1]

Document Type	Document#	File Name	Location
Study Profile		Study profile.d	C:\Users\SEAU\Documents\le-dossier\Study profile.c

☐ Mark for review

Figure 8-5: Package Document Added

- The *Package [Title]* screen appears listing the package details, application information, and documents.

If you would like to add or edit package metadata, follow the steps provided in section 8.3 (Add/Edit Package Metadata). If you would like to provide or edit package level documents, follow the steps provided in section 8.4 (Add/Edit Package Level Documents).

If you would like to finalize the package, follow the steps provided in section 9 (Validate & Finalize an EDSP Package).

The screenshot shows the e-Dossier V 1.05 application window. The title bar reads "e-Dossier V 1.05". The menu bar includes "Home", "Settings", "Help", "About", and "Exit". The main content area is titled "U.S. ENVIRONMENTAL PROTECTION AGENCY" and "Home ► Package [EDSP Order 011001]". On the left, a tree view shows "EDSP Order 011001" expanded. The main panel displays "Package Details:" with an "Add / Edit" button. The details are: Package Name: EDSP Order 011001, Description: (blank), Email: null, Is PRIA: No, Contact Profile: Profile 1. Below this is a "Documents:" section with an "Add / Edit" button. A table lists documents with columns "Type", "Contains CBI?", and "Name". The table contains one row: "Study", "No", and "Study profile.docx". A "Validate" button is at the bottom left of the main panel.

Type	Contains CBI?	Name
Study	No	Study profile.docx

Figure 8-6: Package [Title] Screen

8.2 Continue a Saved EDSP Package

1. From the *Home* screen, select the **Continue Saved Package** button.

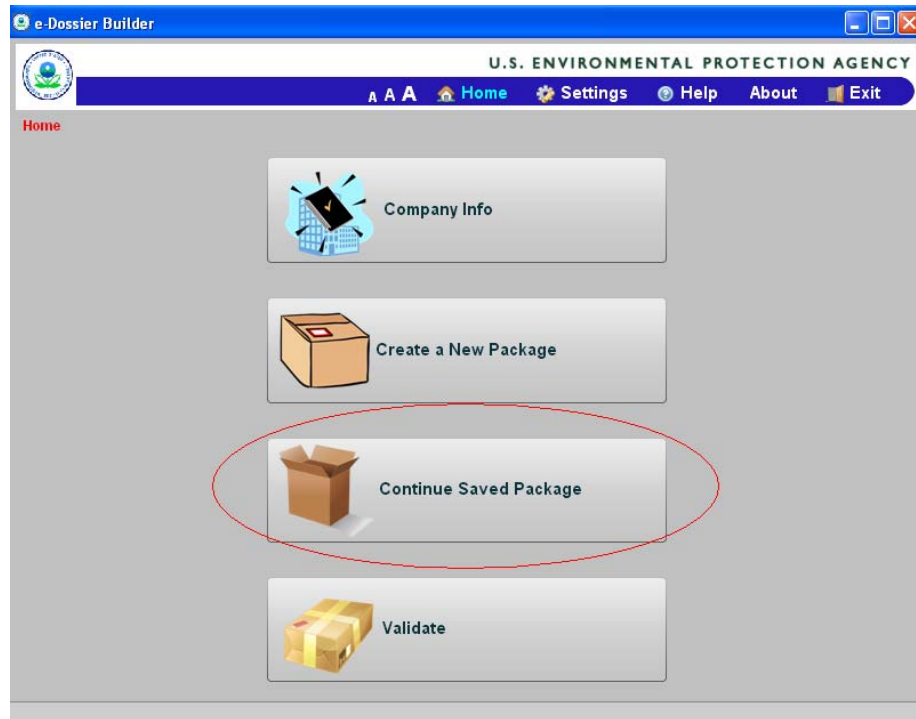


Figure 8-7: Continue Saved Package

- The *Open Package* screen appears and provides a listing of all packages. Click on one of the **packages** listed, and then select the **Open** button.

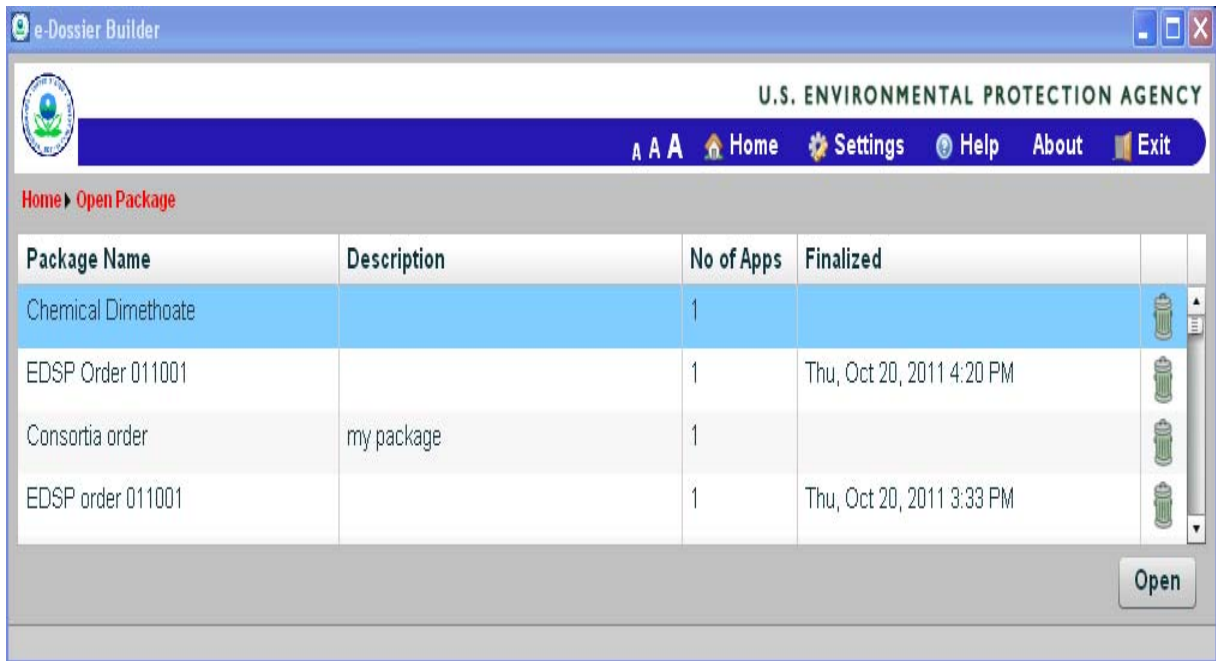


Figure 8-8: Open Package Screen

3. The *Package [Title]* screen appears. Continue with the creation of the package.

The screenshot shows the 'eDossier V 1.05' application window. The title bar includes standard Windows window controls. The main header features the U.S. Environmental Protection Agency logo and a navigation bar with links: Home, Settings, Help, About, and Exit. Below the header, a breadcrumb trail reads 'Home > Package [EDSP Order 011001]'. The left sidebar contains a tree view with 'EDSP Order 011001' selected. The main content area is divided into two sections: 'Package Details' and 'Documents'. The 'Package Details' section has an 'Add / Edit' button and displays the following information: Package Name: EDSP Order 011001, Description: (blank), Email: null, Is PRIA: No, and Contact Profile: Profile 1. The 'Documents' section also has an 'Add / Edit' button and contains a table with one row of data.

Type	Contains CBI?	Name
Study	No	Study profile.docx

At the bottom of the main content area, there is a 'Validate' button.

Figure 8-9: Package [Title] Screen

8.3 Add/Edit Package Metadata

1. From the *Package [Title]* screen, select the **Add/Edit** button provided next to *Package Details*.

The screenshot shows the 'eDossier V 1.05' application window. The title bar includes the text 'eDossier V 1.05' and standard window controls. The main menu bar contains 'U.S. ENVIRONMENTAL PROTECTION AGENCY' and navigation links: 'Home', 'Settings', 'Help', 'About', and 'Exit'. Below the menu bar, a breadcrumb trail reads 'Home > Package [EDSP Order 011001]'. The left sidebar shows a tree view with 'EDSP Order 011001' selected. The main content area is titled 'Package Details' and features an 'Add / Edit' button circled in red. Below this, the package information is displayed as follows:

Package Name	:	EDSP Order 011001
Description	:	
Email	:	null
Is PRIA	:	No
Contact Profile	:	Profile 1

Below the package details, there is a 'Documents:' section with an 'Add / Edit' button. A table lists the documents:

Type	Contains CBI?	Name
Study	No	Study profile.docx

At the bottom of the main content area, there is a 'Validate' button.

Figure 8-10: Package Details Add/Edit

2. The *Package Info* screen appears. Make desired changes, and then select the **View Summary** button to return to the *Package [Title]* screen.

If you would like to provide or edit package documents, select the **Next>** button and go to step 8 of section 8.4 (Add/Edit Package Level Documents).

e-Dossier V 1.05

U.S. ENVIRONMENTAL PROTECTION AGENCY

Home > [EDSP Package] > Edit

Package Info

Package Name * EDSP Order 011001

Description (Package Description is Optional, for internal use by company, not Currently used by EPA)

Company Profile * Profile 2

Next > View Summary

Figure 8-11: Edit Package Info

3. The *Package [Title]* screen appears and the changes made are provided in *Package Details*.

The screenshot shows the eDossier V1.05 application window. The title bar reads "e-Dossier V1.05". The menu bar includes "U.S. ENVIRONMENTAL PROTECTION AGENCY", "Home", "Settings", "Help", "About", and "Exit". The breadcrumb trail shows "Home > Package [EDSP Order 011001]". The left sidebar has a tree view with "EDSP Order 011001" selected. The main content area is titled "Package Details: Add / Edit". It contains the following information:

Package Name: EDSP Order 011001 (circled in red)
Description: :
Email: : null
Is PRIA: : No
Contact Profile: : Profile 1

Below this is a section titled "Documents: Add / Edit" containing a table:

Type	Contains CBI?	Name
Study	No	Study profile.docx

At the bottom left of the main content area is a "Validate" button.

Figure 8-12: Package Info Change

8.4 Add/Edit Package Level Documents

1. From the *Package [Title]* screen, select the **Add/Edit** button provided next to *Documents*.

The screenshot shows the 'e-Dossier V 1.05' application window. The title bar includes the EPA logo and the text 'U.S. ENVIRONMENTAL PROTECTION AGENCY'. The menu bar contains 'Home', 'Settings', 'Help', 'About', and 'Exit'. The breadcrumb trail is 'Home > Package [EDSP Order 011001]'. On the left, a tree view shows 'EDSP Order 011001' expanded. The main content area is titled 'Package Details: Add / Edit' and contains the following information:

Package Name : EDSP Order 011001
Description :
Email : null
Is PRIA : No
Contact Profile : Profile 1

Below this, the 'Documents' section has an 'Add / Edit' button circled in red. Underneath is a table:

Type	Contains CBI?	Name
Study	No	Study profile.docx

A 'Validate' button is located at the bottom left of the main content area.

Figure 8-13: Package Document Add/Edit

2. The *Documents for the Package* screen appears. Add another document or make changes to a previously added document by selecting the document and clicking on the **Edit Document** button. When editing a previously added document, be sure to select the **Save Document** button when finished.

If you would like to delete a document, select the **Delete Document** button.

When complete, select the **View Summary** button.

Note: If adding multiple documents, the last document added will be placed at the bottom of the *Documents* table. Additionally, documents are not officially attached until the package is finalized.

Figure 8-14: Edit Package Document

3. The *Package [Title]* screen appears and the changes made are provided in *Documents*.

e-Dossier V1.05

U.S. ENVIRONMENTAL PROTECTION AGENCY

Home Settings Help About Exit

Home > Package [EDSP Order 011001]

EDSP Order 011001

Package Details: Add / Edit

Package Name : EDSP Order 011001

Description :

Email : null

Is PRIA : No

Contact Profile : Profile 1

Documents: Add / Edit

Type	Contains CBI?	Name
Study	No	Study profile.docx

Validate

Figure 8-15: Package [Title] Screen

4. On the *Document Metadata* screen. If you would like to return to this screen later, select the **Mark for review** box provided on bottom left side of the screen. Select **‘View Summary’** button to go to *Package[Title]* screen

e-Dossier V 1.05

U.S. ENVIRONMENTAL PROTECTION AGENCY

Home >>[EDSP Package]> Documents

Company Document Number

Document Title

Document Author (Use comma as separator)

Document Date *

Document Group (Document Group is Optional, Future Use, not Currently used by EPA)

Contains CBI? * ☐ Yes ☐ No

Guideline Number * 890.1100-Amphibian Metamorphosis 890.1150-Androgen Receptor Binding 890.1200-Aromatase

*Use Shift button to select multiple Guideline numbers

Documents: [1]

Document Type	Document#	File Name	Location
Study Profile		Study profile.d	C:\Users\SEAU\Documents\le-dossier\Study profile.c

☐ Mark for review

Add Document Cancel View Summary

Figure 8-16: Documents Screen

5. The *Package [Title]* screen appears and the *Documents* information is updated with ‘*This section is marked for Review’. Select the **Validate** button to go to the *Validate* screen

e-Dossier V 1.05

U.S. ENVIRONMENTAL PROTECTION AGENCY

Home Package [EDSP Order 011001]

*EDSP Order 011001

Package Details: Add / Edit

Package Name : EDSP Order 011001

Description :

Email : null

Is PRIA : No

Contact Profile : Profile 2

Documents: Add / Edit

*This section is marked for Review

Type	Contains CBI?	Name
Study Profile	No	Study profile.docx

Validate

Figure 8-17: Package [Title] Screen

- The *Validate* screen a message stating ‘*Application [Title] has been marked for review.*’ Click the **Review** button to review the application and the **Finalize** button to finalize the package.

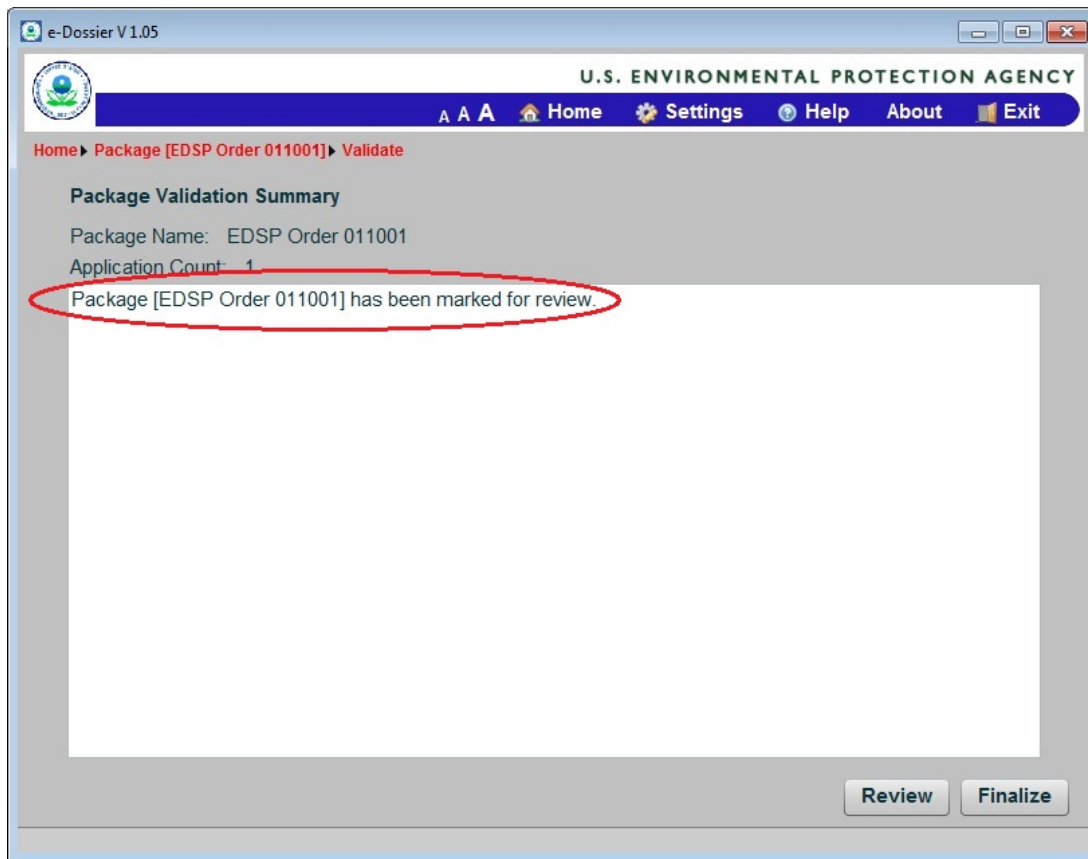


Figure 8-18: Package Validation Summary

- Once all applications, metadata, and documents have been added, the package can be finalized following the steps provided in section 9 (Validate & Finalize an EDSP Package).

8.5 Open Package Level Documents

Note: This can only be completed if you have attached documents to the package.

1. From the *Package [Title]* screen, click on a **document name** provided in the *Documents* table.

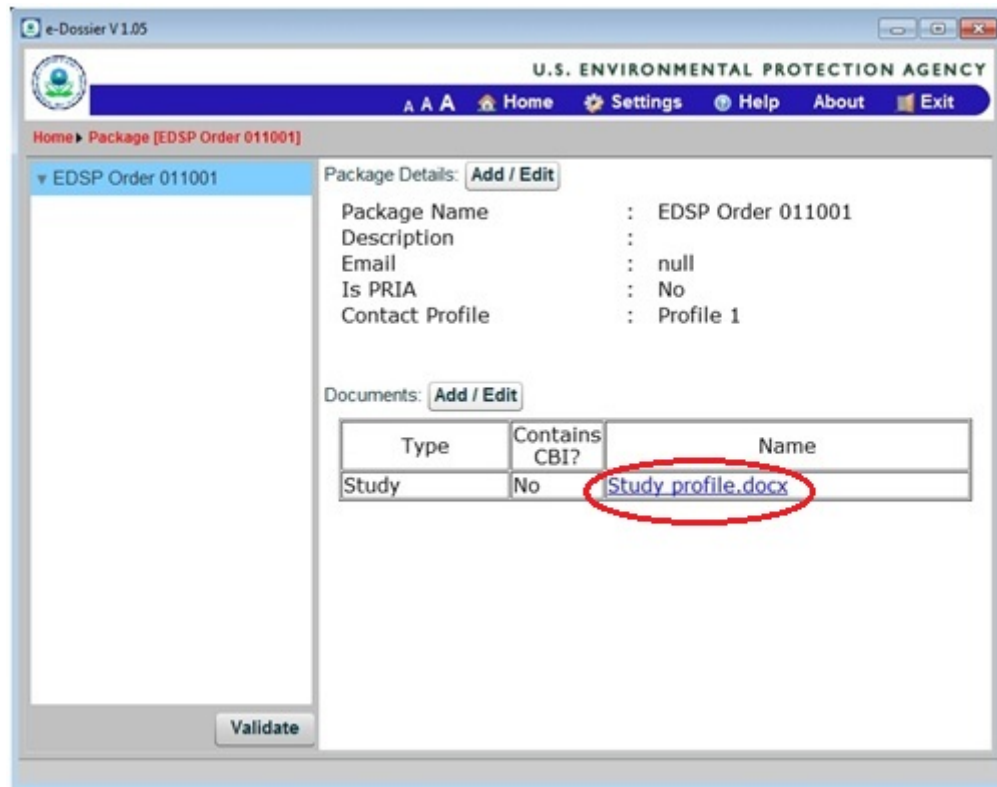


Figure 8-19: Select Package Document

2. The *File Download* window appears. Select the **Open** button.

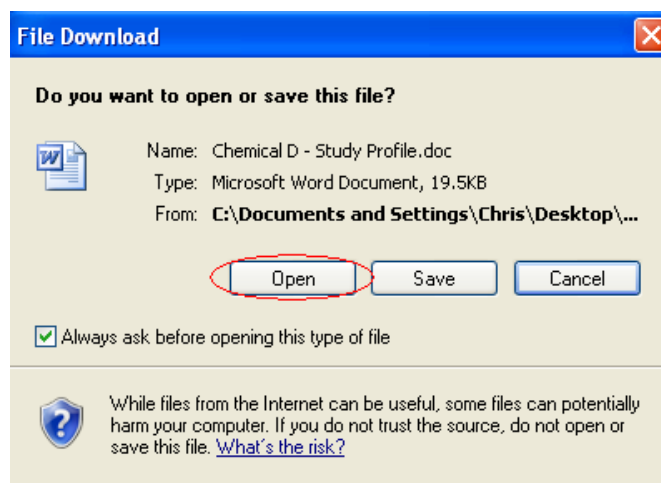


Figure 8-20: File Download Window

3. The document opens in Internet Explorer as demonstrated below.

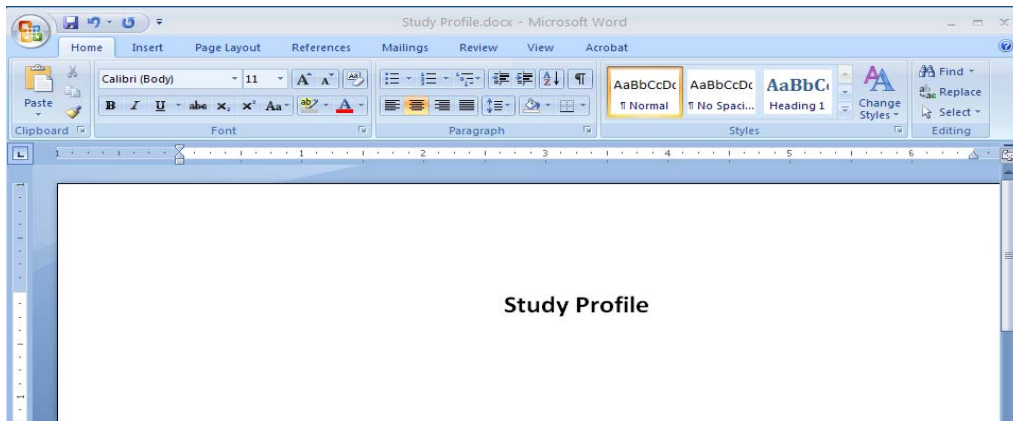


Figure 8-21: Package Level Document

9 Validate & Finalize an EDSP Package

1. From the *Package [Title]* screen, select the **Validate** button.

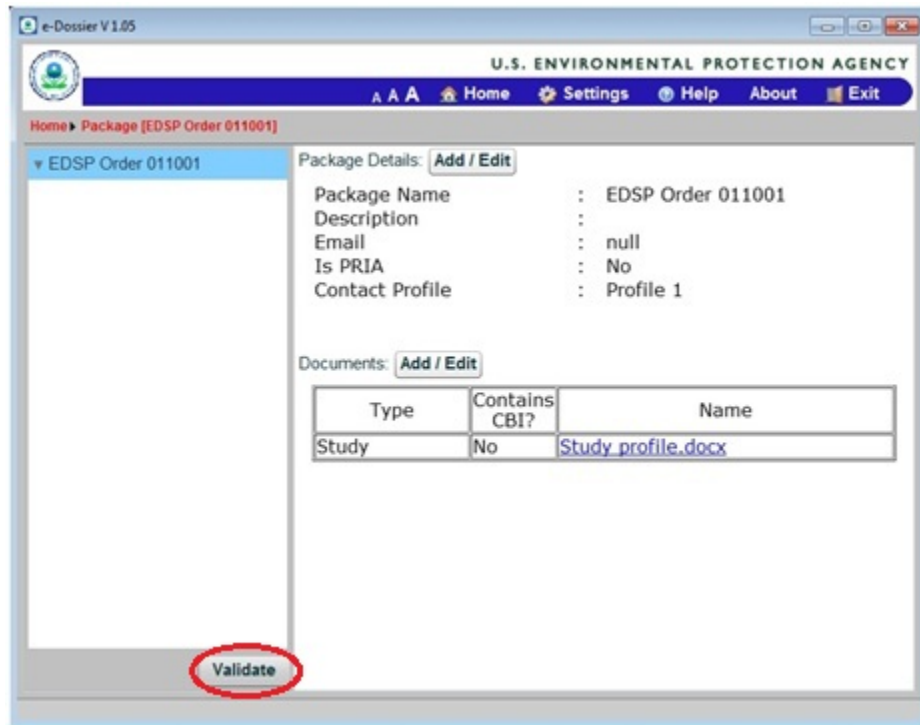


Figure 9-1: Package Validate Button

2. The *Package Validation Summary* screen appears.

If you marked a previous application screen for review, or if errors are found, these are listed on the screen. If so, correct the errors identified and/or review the application screens marked for review.

If not, a message appears stating “The package has been processed successfully.” Select the **Finalize** button.

Note: Once a package is finalized, it can no longer be edited. The package can be ‘Reviewed’ before finalizing the package.

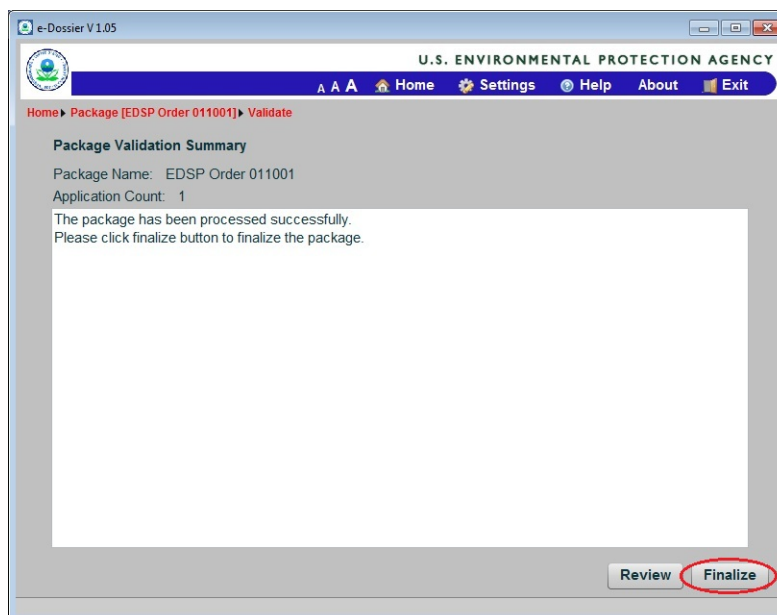


Figure 9-2: Package Validation Summary

3. The *Package Creation Successful* screen appears. If you would like to open the package storage location, select the **Open the contain folder** check box, and then select the **OK** button. If not, just select the **OK** button.

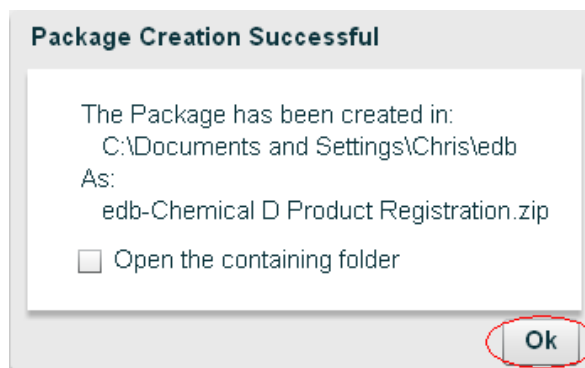


Figure 9-3: Package Creation Successful

4. Once the package has been created, it is now ready to be submitted to EPA. Directions for submitting the package can be found at the EPA OPP electronic submission Web site.

10 Toolbar

Note: Instructions for using the *Help* and *Settings* links are provided in section 11 (System Help) and section 12 (Configuration) respectively.

10.1 Home

1. At any time during the completion of your package, you can return to the *Home* screen. To do so, select **Home** from the tool bar at top of the screen.

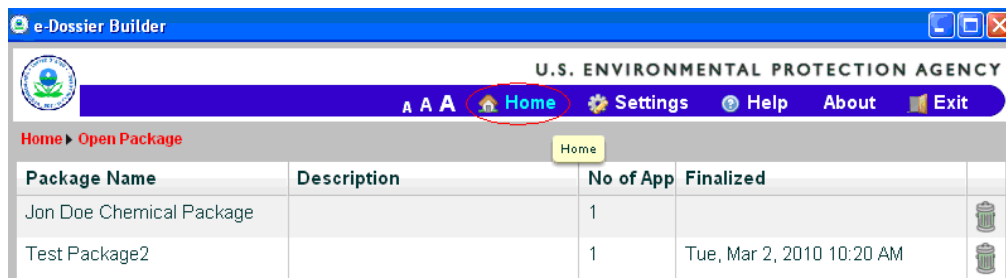


Figure 10-1: Home Link

2. Once selected, the *Home* screen appears.

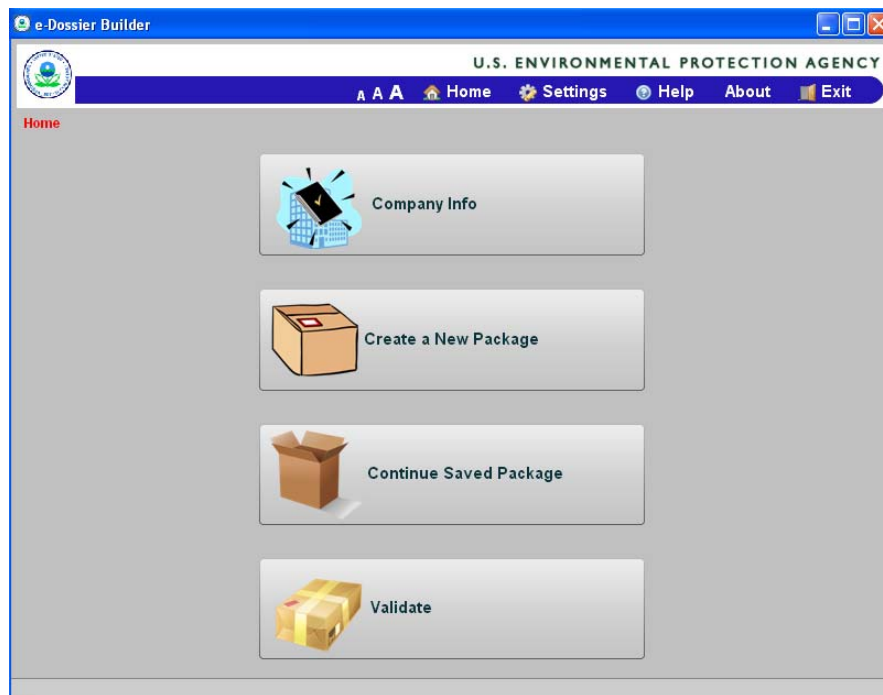


Figure 10-2: Home Screen

10.2 About

1. At any time during the completion of your package, you can view information (e.g., version number, build number, etc.) about the version of eDossier Builder that you are using. To do so, select **About** from the tool bar at top of the screen.

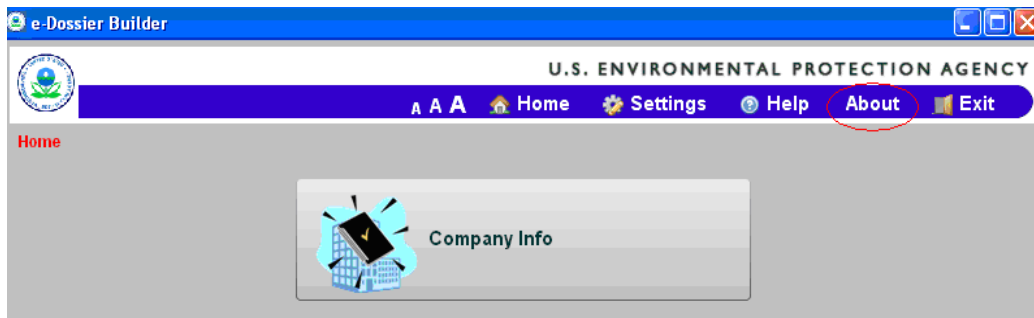


Figure 10-3: About Link

2. Once selected, the *About* screen appears. To close the *About* screen, select the **OK** button.



Figure 10-4: About Screen

11 System Help

If you have questions during the creation of the package, the resources described below are available to assist you.

At any time during the completion of your package, you can view a brief description of a field or button provided on a screen. This can be completed by scrolling over a **field** or **button** as demonstrated below.

The screenshot shows the 'e-Dossier V 1.05' web application interface. At the top, there is a header with the EPA logo and the text 'U.S. ENVIRONM'. Below the header, there is a navigation bar with links for 'Home' and 'Settings'. The main content area is titled 'Package Info' and contains several form fields: 'Package Name' with the value 'Chemical D Product Registration', 'Description' (empty), 'Is this PRIA?' with an unchecked checkbox, and 'Company Profile' with a dropdown menu showing 'Profile 1'. A red oval highlights the 'Company Profile' dropdown, and a yellow tooltip box appears below it with the text 'Company profile for the package.'.

Figure 11-1: Field Tooltip

A full description of the screen and its fields can be viewed by going to the *Help* screen as instructed below.

1. Select **Help** from the tool bar at top of the screen.



Figure 11-2: Help Link

2. Once selected, the *Help Details* screen appears. There is a different screen for EDSP and Non-EDSP packages.

The screen below provides a listing and description of all of the fields provided on the current screen for Non-EDSP package.

To close the *Help* screen, select the **X** button.

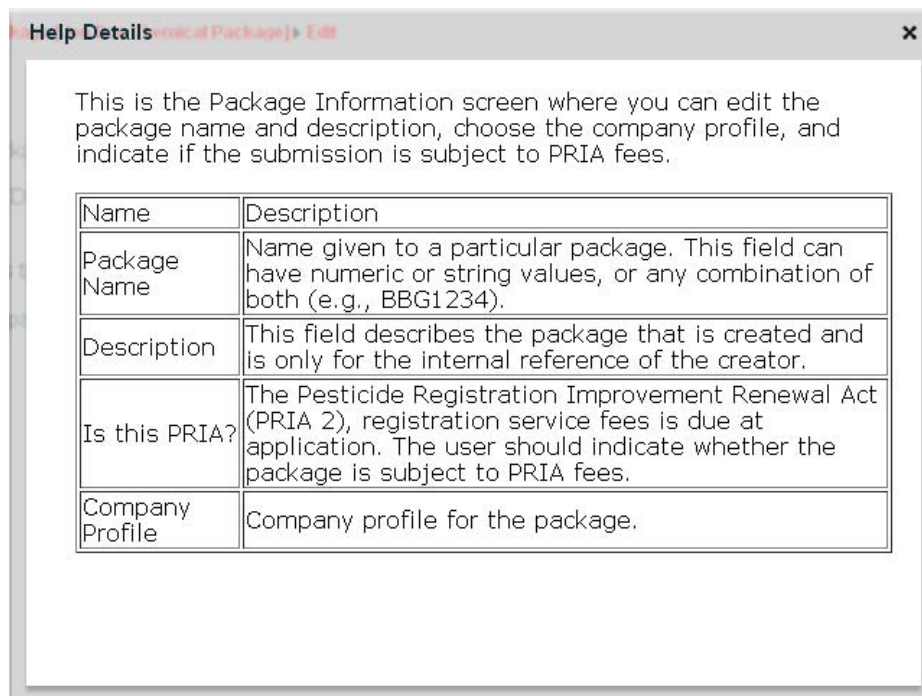


Figure 11-3: Non-EDSP Help Details

Additionally, a complete listing of the field descriptions is provided in Appendix A (Non-EDSP Data Fields).

The screen below provides a listing and description of all of the fields provided on the current screen for Non-EDSP package.

To close the *Help* screen, select the **X** button.

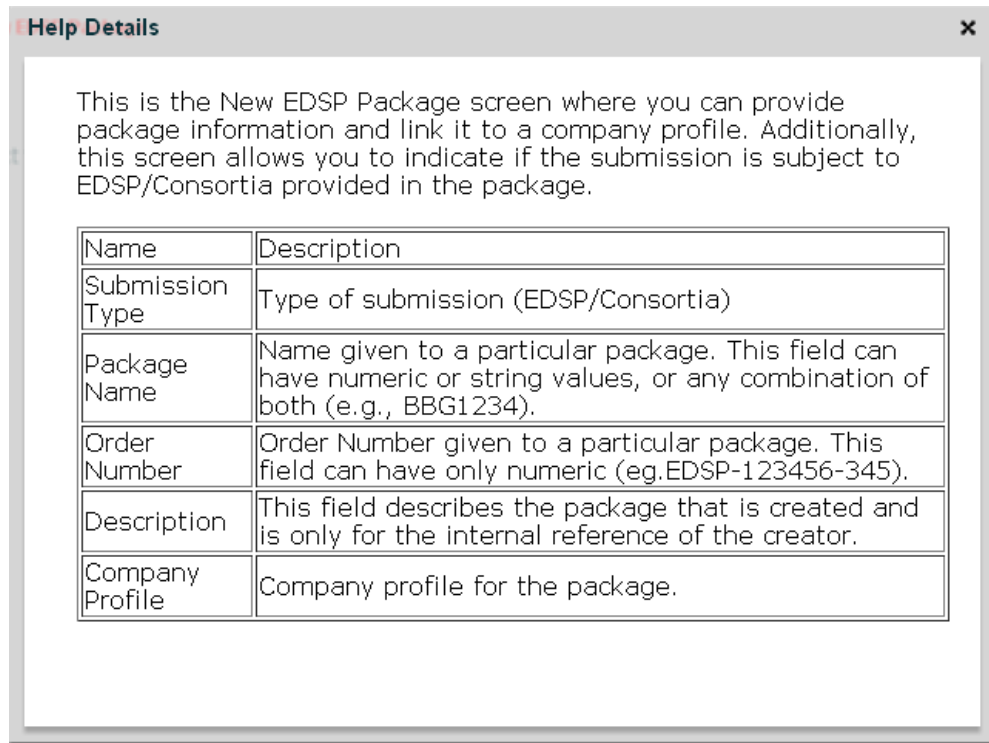


Figure 11-4: EDSP Help Details

Additionally, a complete listing of the field descriptions is provided in Appendix B (Data Fields for EDSP Packages).

12 Configuration

12.1 Package Storage Location

By default, the package you create will be stored at C:\Documents and Settings\username\edb. Follow the steps listed below if you would like to view this setting and/or change the storage location.

1. Select **Settings** from the tool bar provided at the top of screen.

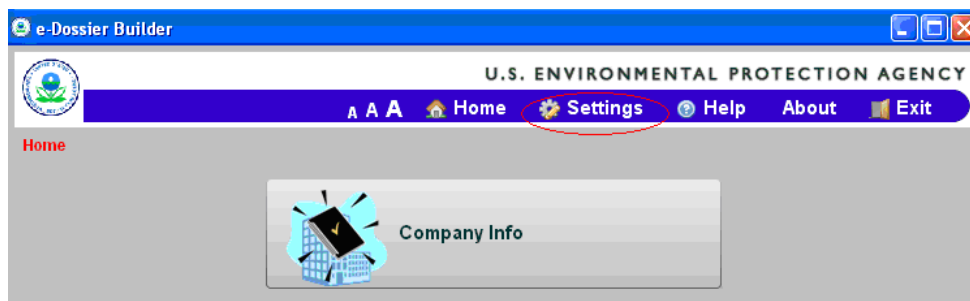


Figure 12-1: Settings Link

2. The *Configuration Settings* screen appears. If you would like to change the file location for storing the eDossier package, select the **Browse...** button.

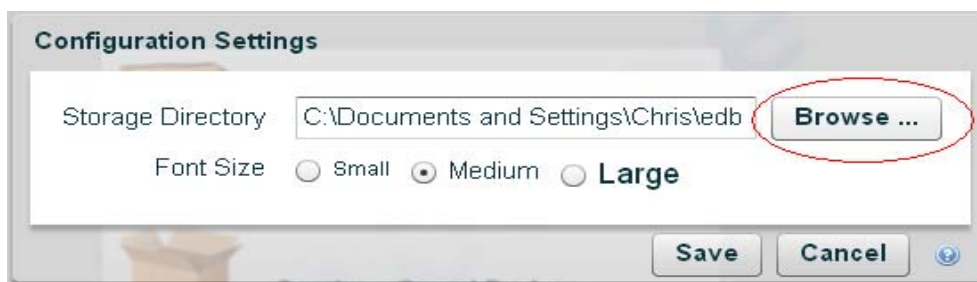


Figure 12-2: Configuration Settings

3. The *Browse For Folder* screen appears. Select a **folder** to store the eDossier package, and then select the **Make New Folder** button.

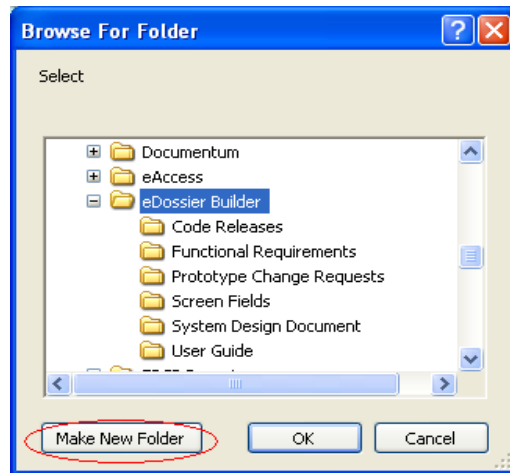


Figure 12-3: Browse For Folder

4. A folder appears titled *New Folder* within the selected folder/location. If preferred, enter a **new name** for the folder and then select the **OK** button.

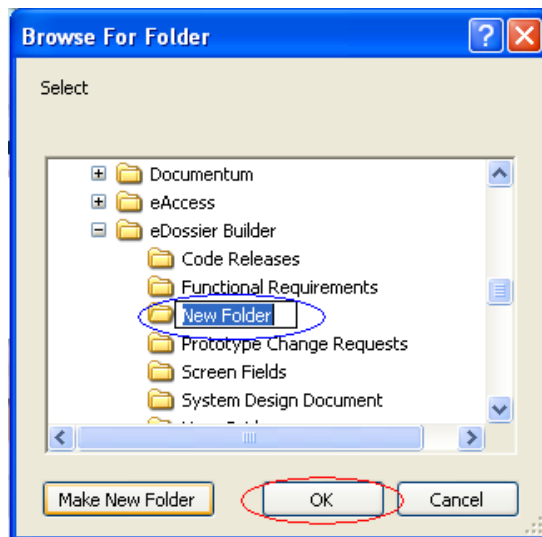


Figure 12-4: New Folder

5. The *Browse for Folder* screen closes and the newly selected location is provided in the *Storage Directory* field of the *Configuration Settings* screen. Select the **Save** button.

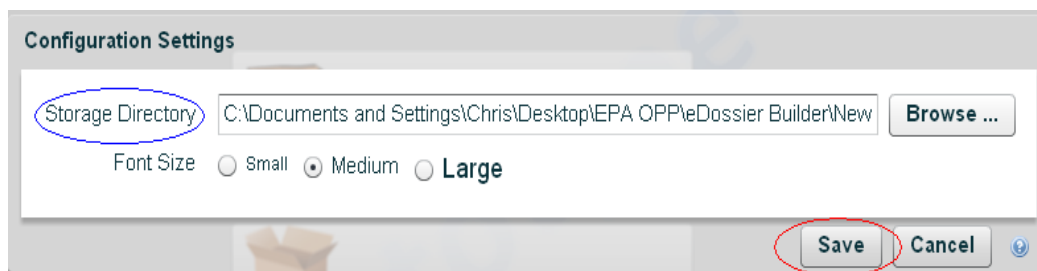


Figure 12-5: Configuration Settings – New Storage Directory

6. The *Configuration Settings* window closes.

12.2 Application Font Size

The application font size can be increased or decreased permanently or on a session basis. The instructions to change the font size for each are provided below.

12.2.1 Permanent

1. Select **Settings** from the tool bar provided at the top of screen.

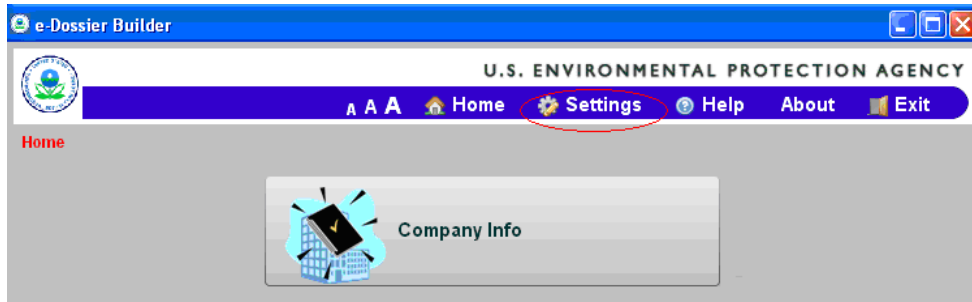


Figure 12-6: Settings Link

2. The *Configuration Settings* screen appears. The default font size for the application is Medium. Select the **Small** or **Large** radio button if you would like to decrease or increase the font size, and then select the **Save** button.

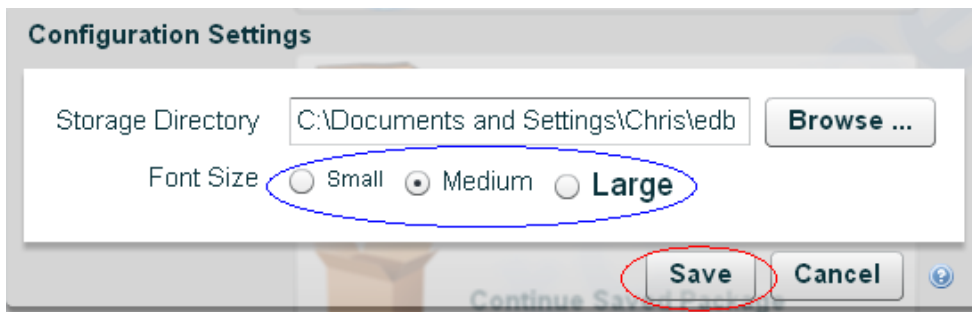


Figure 12-7: Configuration Settings – Font Size

Note: The selected font size will appear throughout the application until it is changed again.

12.2.2 Current Session

If you would like, you can change the application font size for only the current session from any application screen. By default, the application font size is set to Medium. As shown below, the left A is for a Small font, the middle A is for a Medium font, and the right A is a Large font.

Select the desired **font size**. The font size should change on the current screen and all other application screens.

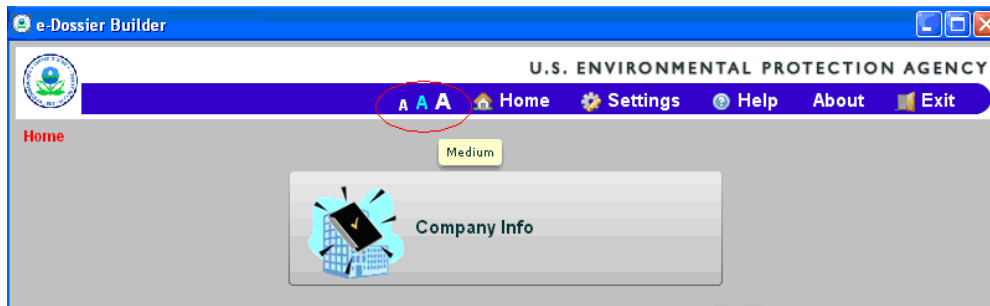


Figure 12-8: Session Font

Note: The font size will remain throughout the session and will change back to the default or previously saved (see Section 12.2.1 – Permanent) font size after the session is terminated.

13 Exit

1. Select **Exit** from the tool bar provided at the top of screen.



Figure 13-1 Exit Link

2. The *Close* window appears asking if you would like to close the application. Select the **Yes** button.

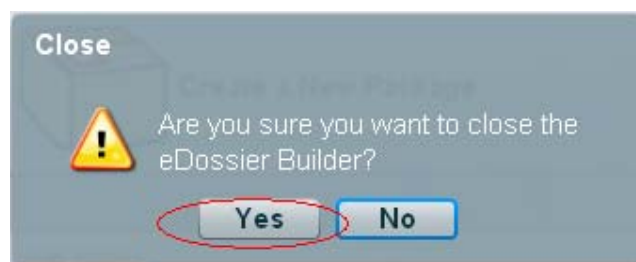


Figure 13-2: Close Window

3. The application closes.

Appendix A: Non-EDSP Data Fields

Provided below is a table that lists all the data fields and description of each that is provided in Tool Tips and on the *Help* screen.

Field Name	Tool Tips	Help
Address <i>*Formal Change to the existing company address can be made only by contacting EPA not through this application.</i>	Street address of the company.	Street address of the company.
Administration Number/Registration Number	This field should contain the Admin Number, tolerance petition number, experimental use permit number, registration number, or SLN number.	1. Must have between 4 and 50 characters. 2. Cannot contain spaces.
Application Name	Name given to the application that is to be created. This name will be the name displayed in the summary screen.	Name given to the application that is to be created. This name will be the name displayed in the summary screen.
Application Type	List of all Application types that can be added or registered.	List of all Application types that can be added or registered.
Author	Person in charge for the contents of the document.	Person in charge for the contents of the document.
City	City where the company is located.	City where the company is located.
Comment (for Company Information) <i>*Optional, Future Use ,not Currently used by EPA</i>	Field for the submitting company to comment on the company profile created. This is for internal reference of the company.	Field for the submitting company to comment on the company profile created. This is for internal reference of the company.

Field Name	Tool Tips	Help
Comments(for Documents attached with the application) <i>*Optional, future use ,not currently used by EPA</i>	Field for the submitting company to comment on the document being submitted.	Field for the submitting company to comment on the document being submitted.
Company Document Number <i>*Optional, future use ,not currently used by EPA</i>	This is a field is for providing the internal reference of the registrant and specifies the document number for the document submitted by the registrant.	This is a field for providing the internal reference of the registrant and specifies the document number for the document submitted by the registrant.
Company Name	Indicates the name of the company.	Indicates the name of the company
Company Number	Indicates the company number assigned by EPA.	Indicates the company number assigned by EPA.
Contains CBI	Indicates whether the contents of the document are confidential or not.	Confidential Business Information field can have any of the two values (Yes/No). Yes indicates it contains CBI, and no indicates it does not contain CBI. It is the discretion of the user to mark a document as confidential or non-confidential.
Country	Displays the country of the company.	Displays the country of the company.
Description (for Profile) <i>*Optional, for internal use by company, not currently used by EPA</i>	Description given to the profile created.	This field describes the profile that is created and is only for the internal reference of the creator.
Description (for Package) <i>*Optional, for internal use by company, not currently used by EPA</i>	Description given to the package created.	This field describes the package that is created and is only for the internal reference of the creator.

Field Name	Tool Tips	Help
Description/Remarks (for Application) <i>*Optional, future use ,not currently used by EPA</i>	Allows the submitting company to provide questions, notes, or other remarks. The submitting company may enter any value they wish into this field.	Allows the submitting company to provide questions, notes, or other remarks. The submitting company may enter any value they wish into this field.
Document Date	Specify a date to be linked to the document (e.g., the creation date).	Specify a date to be linked to the document (e.g., the creation date).
Document Group <i>*Optional, future use ,not currently used by EPA</i>	Specify the document group to which the document is related.	Specify the document group to which the document is related.
Document Location	File location of the document.	File location of the document.
Document Title	Title given for the document.	Title given for the document.
Document Type	Select the document type for the application.	Select the document type for the application.
Email	Email address of the company contact person.	Email address of the company contact person.
Email [Package Info]	Email address of the Regulatory contact person.	Email address of the Regulatory contact person.
EPA MRID Number <i>*Root MRID Number will be associated with this particular application in this package and cannot be reused with any other application/packages.</i>	Refers to the MRID of the study being submitted by the company or its lab.	Refers to the MRID of the study being submitted by the company or its lab. For Study Profiles/Summaries and supplemental study data, use the MRID of the parent study. MRIDs must be pre-assigned by EPA.

Field Name	Tool Tips	Help
Fast Track	Enter a Fast Track Indicator for particular Regulatory Type – Application Type combinations.	Enter a Fast Track Indicator for particular Regulatory Type – Application Type combinations. The only acceptable values for the Fast Track Indicator field are as follows: o Yes o No
Guideline Number	Indicates the “Guideline Number” associated with a study.	Indicates the “Guideline Number” associated with a study. Provided only for Study documents. However, if the study does not have a guideline number or the number entered is invalid, the package can still be successfully created.
Lap Report Number	Refers to the internal identification number for a study used by the lab that produced the study.	Refers to the internal identification number for a study used by the lab that produced the study.
Me-Too Indicator	A “final” Me-Too Indicator for particular Regulatory Type – Application Type combinations.	A “final” Me-Too Indicator for particular Regulatory Type – Application Type combinations. A "Me-Too" pesticide registration application refers to a request to register a new pesticide product that is identical in its uses and formulation, substantially similar in its uses and formulation to one or more products currently registered and marketed in the United States, or differing only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment.

Field Name	Tool Tips	Help
Name	Name of the company contact person.	Name of the company contact person.
Package Name <i>*Optional, for internal use by company, not currently used by EPA</i>	Name given to a particular package.	Name given to a particular package. This field can have numeric or string values, or any combination of both (e.g., BBG1234).
Page count	Refers to the number of pages in a study.	Refers to the number of pages in a study (including appendices) that is provided by the submitting company or its lab. The value entered should be numeric.
Petition Type	A “final” Petition Type for particular Regulatory Type – Application Type combinations.	<ul style="list-style-type: none"> • The acceptable values for the Petition Type field will be dependent on the “Petition Number Type” segment of the Petition Number (the single character that follows the “Year”). • If the “Petition Number Type” is “E”, the acceptable values for the Petition Type field will be as follows: <ul style="list-style-type: none"> o Minor Use (IR-4/State) o Minor Use (Not IR-4) o Inert (Not IR-4) o Import • If the “Petition Number Type” is “F”, the acceptable values for the Petition Type field will be as follows: <ul style="list-style-type: none"> o Raw Agricultural Commodity • If the “Petition Number Type” is “G”, the acceptable values for the Petition Type field will be as follows: <ul style="list-style-type: none"> o Temporary

Field Name	Tool Tips	Help
		<ul style="list-style-type: none"> • If the “Petition Number Type” is “H”, the acceptable values for the Petition Type field will be as follows: <ul style="list-style-type: none"> o Food Additive o Temporary Food Additive
Phone	Phone number of the company contact person.	Phone number of the company contact person.
Postal code	Postal code of the location where the company is located.	Postal code of the location where the company is located.
PRIA <i>*Optional, future use ,not currently used by EPA</i>	Is this package subject to PRIA Fees?	The Pesticide Registration Improvement Renewal Act (PRIA 2), registration service fees is due at application. The user should indicate whether the package is subject to PRIA fees.
Product Name	This field contains the name associated with the product.	This field contains the name associated with the product.
Profile Name <i>*Optional, for internal use by company, not currently used by EPA</i>	Name given to the profile created. The Profile name created is for internal reference.	Name given to the profile created. This field can have numeric or string values, or any combination of both (e.g., alpha01).
Refer already submitted document	Reference to a document that has already been submitted.	Reference to a document that has already been submitted. Please note that a reference number (e.g., MRID number) is required to be mentioned.
Referred document MRID Number	The MRID number of a document that has already been submitted.	The MRID number of a document that has already been submitted. Please note that the MRID number is required to be mentioned.

Field Name	Tool Tips	Help
Regulatory Type	List of all Regulatory types that are selected for the Application type.	List of all Regulatory types that are selected for the Application type.
Is this an initial submission?	Field indicates whether the application is a resubmission.	Field indicates whether the application is a resubmission.
Risk Manager	The Risk Manager for the Regulatory type- Application type. (example 01)	The Risk Manager for the particular Regulatory type- Application Type should be provided. The information to be provided includes the following: o Division Name o Team Name (example 01)
State	State where the company is located.	State where the company is located.
Title (Contact Person Title)	Title of the contact person. This could mean a person other than the one submitting the package.	Title of the contact person.

Appendix B: Data Fields for EDSP Packages

Provided below is a table that lists all the data fields and description of each that is provided in Tool Tips and on the *Help* screen.

Field Name	Tool Tips	Help
Address <i>*Formal Change to the existing company address can be made only by contacting EPA not through this application.</i>	Street address of the company.	Street address of the company.
City	City where the company is located.	City where the company is located.
Comment (for Company Information) <i>*Optional, Future Use ,not Currently used by EPA</i>	Field for the submitting company to comment on the company profile created. This is for internal reference of the company.	Field for the submitting company to comment on the company profile created. This is for internal reference of the company.
Comments(for Documents attached with the application) <i>*Optional, future use ,not currently used by EPA</i>	Field for the submitting company to comment on the document being submitted.	Field for the submitting company to comment on the document being submitted.
Company Document Number	This is a field is for providing the internal reference of the registrant and specifies the document number for the document submitted by the registrant.	This is a field for providing the internal reference of the registrant and specifies the document number for the document submitted by the registrant.
Company Name	Indicates the name of the company.	Indicates the name of the company.

Field Name	Tool Tips	Help
Company Number	Indicates the company number assigned by EPA.	Indicates the company number assigned by EPA.
Company Profile	Company profile for the package.	Company profile for the package.
Contains CBI	Indicates whether the contents of the document are confidential or not.	Confidential Business Information field can have any of the two values (Yes/No). Yes indicates it contains CBI, and no indicates it does not contain CBI. It is the discretion of the user to mark a document as confidential or non-confidential
Country	Displays the country of the company.	Displays the country of the company.
Description (for Profile) <i>*Optional, for internal use by company, not currently used by EPA</i>	Description given to the profile created.	This field describes the profile that is created and is only for the internal reference of the creator.
Description (for Package) <i>*Optional, for internal use by company, not currently used by EPA</i>	Description given to the package created.	This field describes the package that is created and is only for the internal reference of the creator.
Document Author	Person in charge for the contents of the document.	Person in charge for the contents of the document.
Document Date	Specify a date to be linked to the document (e.g., the creation date).	Specify a date to be linked to the document (e.g., the creation date).
Document Group <i>*Optional, future use ,not currently used by EPA</i>	Specify the document group to which the document is related.	Specify the document group to which the document is related.

Field Name	Tool Tips	Help
Document Location	File location of the document.	File location of the document.
Document Title	Title given for the document.	Title given for the document.
Document Type	Select the document type for the application.	Select the document type for the application.
Email	Email address of the company contact person.	Email address of the company contact person.
EPA MRID Number	Refers to the MRID of the study being submitted by the company or its lab.	Refers to the MRID of the study being submitted by the company or its lab. For Study Profiles/Summaries and supplemental study data, use the MRID of the parent study. MRIDs must be pre-assigned by EPA.
Guideline Number	Indicates the “Guideline Number” associated with the document.	Indicates the “Guideline Number” associated with the document submitted. Displays the guideline number for the 11 assays.
Key Type	Indicates whether a study has been published and made publicly available.	Indicates whether a study has been published and made publicly available.
Lap Report Number	Refers to the internal identification number for a study used by the lab that produced the study.	Refers to the internal identification number for a study used by the lab that produced the study.
Name	Name of the company contact person.	Name of the company contact person.
Order Number	This field should contain the EDSP or Consortia Order Number.	The order number must have maximum of 12 digits which is the PCcode and the sequence number. The order number will be prefixed by 'EDSP' for EDSP orders and 'CON' for consortia orders.

Field Name	Tool Tips	Help
Package Name	Name given to a particular package.	Name given to a particular package. This field can have numeric or string values or any combination of both (e.g., BBG1234).
Phone	Phone number of the company contact person.	Phone number of the company contact person.
Postal code	Postal code of the location where the company is located.	Postal code of the location where the company is located.
Risk Manager	The Risk Manager for the Regulatory type- Application type. (example 01)	The Risk Manager for the particular Regulatory type- Application Type should be provided. The information to be provided includes the following: o Division Name o Team Name (example 01)
Select the Submission Type	List of all Application types that can be added or registered. This will be either EDSP or Consortia.	List of Submission types (EDSP or Consortia) that can be submitted.
State	State where the company is located.	State where the company is located.
Title	Title of the contact person. This could mean a person other than the one submitting the	Title of the contact person.

Field Name	Tool Tips	Help
	package.	